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NATIONAL CANCER INSTITUTE'S MANAGEMENT OF RADIATION STUDIES

HEARING

BEFORE THE

PERMANENT
SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

SEPTEMBER 16, 1998

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NATIONAL CANCER INSTITUTE'S MANAGEMENT OF RADIATION STUDIES

WEDNESDAY, SEPTEMBER 16, 1998

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:38 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Subcommittee, presiding.

Present: Senators Collins, Glenn, and Durbin.

Staff Present: Timothy J. Shea, Chief Counsel/Staff Director; Mary D. Robertson, Chief Clerk; Pamela Marple, Minority Chief Counsel; David McKean, Minority Staff Director; Bob Roach, Counsel to the Minority; Beth Stein, Counsel to the Minority; Bill McDaniel, Investigator to Minority; John Neumann, Investigator (Detailee, GAO); Kirk E. Walder, Investigator; Lindsey E. Ledwin, Staff Assistant; Felicia Knight (Sen. Collins); Chris Dockerty, (Sen. Thompson); Kevin Mathias (Sen. Specter); Len Weiss (Governmental Affairs/Sen. Glenn); Marianne Upton, (Sen. Durbin); Lynn Kimmerly and Donna Berry (Sen. Cleland); Gabriel Goldstein (Sen. Lieberman); and Antigone Popamianos (Sen. Levin).

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. The Subcommittee will please come to order.

Today, the Permanent Subcommittee on Investigations will examine the National Cancer Institute's management of an important scientific study which assessed the radiation effects of nuclear weapons tests. This hearing is the result of an investigation initiated and led by the Ranking Minority Member, the distinguished Senator from Ohio. Senator John Glenn and his staff should be commended for their work on this investigation, which expanded on an earlier effort by two of our colleagues. This matter was first raised by Senators Arlen Specter and Tom Harkin at a Senate Appropriations Subcommittee hearing held in October 1997, and I want to commend them for their leadership as well.

Our focus this morning is on one particularly significant government study that assessed the exposure of the American people to radiation from government nuclear weapons testing in the 1950's, a study that took 14 years to complete. We will explore whether or not management problems delayed this report, and if so, how to ensure that such problems do not affect future studies managed by the National Cancer Institute or the Department of Health and Human Services.

By way of background, in 1983, the Congress directed the Department of Health and Human Services to assess the potential exposure of the American people to Iodine–131, one of the radioactive elements in the fallout from aboveground nuclear tests. Assessing the health risks facing the public as a result of this exposure was also part of this directive. The Department delegated the task of conducting this review to the National Cancer Institute, which finally released its lengthy study in October 1997.

The findings in the NCI study were sobering, to say the least. Besides the known areas of contamination around the Nevada test site, the data showed that many other parts of the country were also contaminated because weather patterns at the time disbursed radioactive material across America. For some of the nuclear tests, the report found, people as far away as Aroostook County, Maine, where I was born and grew up, may have received as much exposure to radiation as people living in Nevada and Utah.

It came as a real shock to me when I read this part of the report and looked at the maps that outline the States that had received the highest radiation exposure.

In addition, individuals who were young children at the time of the testing and who drank large quantities of locally produced milk received significantly higher concentrations of radiation than did adults in the same area.

This investigation raises important policy questions about openness and trust in government. Did the Federal Government fulfill its duty to report its findings to the American people? Specifically, why was the report published 14 years after it was commissioned and without the important public health information about the risk of cancer associated with the aboveground nuclear tests? Did the Department of Health and Human Services fulfill its duty to see that this study was done in a complete and timely manner, as directed by Congress? And, finally, what are the public health implications of this study as assessed by the report published by the National Academy of Sciences?

The survival of public institutions in a democracy depends on the public's trust and faith in them—in their competence, their integrity, and their fundamental honesty. Studies with potentially significant health implications must be communicated to the American people as soon as possible to ensure public confidence in the Federal agencies responsible for such areas.

To explore the issues surrounding this radiation study, we will hear from several witnesses this morning. Our first witness is the distinguished Senator from Iowa, Senator Tom Harkin. He has a deeply personal interest in this matter and also serves as the Ranking Minority Member of the Labor, Health and Human Services, and Education, Subcommittee of the Appropriations Subcommittee.

Our next panel of witnesses consists of Dr. Owen Hoffman and Dr. Barry Johnson, who will testify about the significance of the NCI's findings on the radiation resulting from nuclear weapons testing.

We will then hear from Dr. Bruce Wachholz, the NCI official who managed the radiation study, who will address why the NCI took 14 years to issue the report.

Our final witness this morning is Dr. William Raub, Deputy Assistant Secretary for Science Policy and Science Advisor to the Secretary of the Department of Health and Human Services.

We look forward to hearing all of this testimony.

Before recognizing the distinguished Senator from Ohio, I would like to set the record straight about certain representations that have been made to the press about this investigation and hearing. I was concerned to read in one report that “a Senate panel” suggested that the project director in this case had a conflict of interest and that “a U.S. Senate investigation” reached a final conclusion about this matter before this hearing. Let me make clear that no such finding has been made and no such conclusions have been reached. Indeed, that is why we are here today. That is the purpose of this hearing, and we are here to listen to the evidence and explore the facts with an open mind. Certainly, there have been no findings or conclusions reached by this Subcommittee, and I just want the record to be clear on those matters.

As I mentioned earlier, this investigation was directed, initiated, and led by the minority staff, and Senator Glenn may have more to say about this issue. At this time, I would like to recognize my colleague, the distinguished Senator from Ohio, Senator Glenn, for any comments that he might have.

OPENING STATEMENT OF SENATOR GLENN

Senator GLENN. Thank you very much, Madam Chairman.

The problems here started back 40-some years ago, back in the days of the Cold War, and over the past several years, the American people have learned about the sad legacy of the U.S. nuclear weapons testing program. Going clear back into the 1950’s and spurred by an overwhelming sense of national security, which many of us here today are old enough to remember where the Cold War was preeminent and where we did a lot of things that, in retrospect or in 20/20 hindsight, we probably would do a lot differently today. But those were the days when the priorities were in a little different direction than they are today.

With the sense of national security, the Federal Government failed to inform the public of the nuclear testing program’s potential dangers as a result of nuclear fallout. And making matters worse, for many years our government continued to hide those facts from the public despite mounting evidence that people, particularly young people, may have been harmed.

The history is by now well documented, and to its credit, the Congress has played an important role in reconstructing that history. We worked hard to open up the files. We worked hard to make sure that current as well as future studies on radiation health effects are as transparent as they should have been for the nuclear testing program during the 1950’s. We have worked to make both the nature of the research and the results of any study accessible to the public so Americans know what the dangers are, and, if they can take precautions of some kind with their children or themselves, even at this late date, that those be available to them.

Overall, we have made progress with these reform efforts, but the struggle is ongoing. I have recently introduced legislation that would ensure that no one will ever be subject to governmental experimentation of any kind without their knowledge and informed consent. This is just common sense. In addition, this Committee has passed some legislation in the past regarding some of the things that happened with radiation studies in Cincinnati. Some of you that have followed the work of this Committee will be familiar with that legislation.

Today, we are going to examine the management and openness of one particular research effort, one with a long history. It started back some 15 years ago when Congress passed an amendment to the Orphan Drug Act directing the Secretary of the Department of Health and Human Services to provide the public with complete information on both the amount and effects of the radioactive iodine released into the atmosphere during the aboveground nuclear weapons testing program conducted by the Federal Government in Nevada in the 1950's and early 1960's. This task was delegated to the National Cancer Institute and only last year, in 1997, some 14 years after receiving a mandate from Congress, did the NCI complete its report.

Although this hearing will not attempt to evaluate all the science underlying the report, it is worth briefly recapitulating NCI's most significant findings. They are that the weapons test distributed high levels of nuclear fallout across the country—I mean clear across the country, too, as the Chairman just stated, some in a particular area because of the vagaries of weather patterns and so on in Maine, about as far as you could get and still be in the continental United States. So it came down in that area where she grew up, literally. We are not implying that you have any effects from this, of course, and we hope you do not, but that just shows how far these things go sometimes, quite apart from where the test actually occurred.

In a number of other areas, including the Northern Plains, the Midwest, and Northeast, individuals received doses of I–131 to their thyroid that were comparable to and in some cases exceeded the doses received by citizens living near the test site in Nevada.

Second, Americans across the Nation received doses of radiation at levels that were much higher than previously believed. It is estimated that 3.5 million children received an average cumulative dose of 10.3 rads of Iodine–131. Some children in certain areas may have received cumulative doses as high as 100 rads.

Also, NCI has since estimated that 11,000 to 212,000 people, which is quite a wide spread, we would acknowledge, which may show some of the difficulties in assessing some of the dangers from this, that those numbers of people may develop radiation-induced thyroid cancer from the weapons test fallout. Fortunately, this type of cancer is rarely life-threatening, but it is in some cases, of course.

When I saw the important information revealed in this report, I was particularly concerned that it took 14 years to complete the study. I asked the staff of the Subcommittee to look into the matter and was quite surprised and disappointed by what we have found.

Before getting into what our investigation uncovered, I would first like to address the same item that the Chairman addressed a moment ago regarding a news story that appeared yesterday and another one this morning, but particularly the one yesterday that appeared alleging that this Subcommittee challenged the ethics of Dr. Wachholz during the NCI's I–131 study. The reporter quoted from a preliminary draft of an internal memorandum which I had never seen or approved. I should add, however, that this article did not mention the finding of that memorandum "that the Subcommittee found no evidence to suggest any potential conflicts affected the I–131 report in any way."

I want to state for the record, and very emphatically, that I do not challenge the ethics of Dr. Wachholz and that today's hearing is focused instead on the management and issuance of the I–131 report itself.

Let's turn to some of the problems with the I–131 report. It was delayed at least 4 years, perhaps longer. The NCI study was plagued by trouble with management, lack of internal oversight, and lack of public participation and openness. In addition, the NCI's participation in ongoing and critical studies of the Chernobyl accident is facing similar difficulties with management. And finally, the Department of Health and Human Services did not have any department-wide policies or guidelines governing the conduct of sensitive studies related to radiation health effects research, even though its agencies now perform many of those studies for the government.

Once again, it would appear that the government has dropped the ball in this case, and citizens who were unknowingly or unwillingly exposed to fallout are again victims of unacceptable bureaucratic indifference or neglect.

NCI's work on the I–131 report is a case study on how not to manage this type of research and a strong reminder we have to constantly work at cultivating openness and public participation in this area. I would add that when Congress or a committee or individuals are given assurance that a research project is being carried out, then it should be expeditiously brought to the fore when the information is ready and should be brought out just as fast as we possibly can.

Again, I want to reiterate that today's hearing is not an attempt to evaluate the science underlying the I–131 report. This morning I hope we can understand why it took so long to get the report out; second, get a better handle on whether or not the NCI report meets the congressional mandate it was given; and third, see what HHS is doing and will do to address the problems with the Chernobyl study to ensure consistent application of openness and public participation through the Department in future studies of radiation health effects.

In sum, I hope this hearing will be one more step toward making government more accountable, open and trustworthy of the faith of the people of this country.

I want to thank you, Madam Chairman, for allowing the Minority to pursue this investigation. We are sorry that the leak occurred. That should not have occurred from whatever source. There was distribution, as I understand it, of this material earlier, and we can discuss that privately later on. We are looking into it ourselves.

So I look forward to hearing from the witnesses this morning and hearing their testimony.

Senator COLLINS. Thank you, Senator.

Our first witness this morning is the distinguished Senator from Iowa, Senator Tom Harkin. I want to commend him for both his personal and professional commitment to this issue. He has been a real leader, along with Senator Arlen Specter, and we very much appreciate his making the time today to come and share his knowledge with us.

We do have a large number of witnesses, so I would ask, if you could, that you limit your comments to about 10 minutes. Thank you.

TESTIMONY OF HON. TOM HARKIN,[1] A U.S. SENATOR FROM THE STATE OF IOWA

Senator HARKIN. I will try to be more brief than that.

Madam Chair, thank you very much and, Senator Glenn, again, thank you for your kind comments, and thank you for holding this hearing. I think it comes at just the right time, and it is covering an issue that I think is of vital importance to all Americans. Maybe it is not the biggest news story today, but it is one that I think is going to affect a lot of people's lives in this country. So your hearing just couldn't be more timely.

Madam Chair, again, I thank you for holding this hearing. I think both you and Senator Glenn really covered it. I don't know that I can add too much more than perhaps just to reinforce a couple of things that you said.

I think both of you hit it just right. It has to do with responsibility and what is the responsibility of the Federal Government at this time. The lack of a medical warning and response to the nuclear weapons testing of the 1950's and 1960's was a huge failure of our government. Again, Senator Glenn is right that it is 20/20 hindsight. Of course, we were living in a different time, a different era, in a Cold War; but, nonetheless, the government still can't escape the responsibility that we have today.

Unfortunately, the lack of response seems to be continuing, and despite some efforts by the NCI and the Institute of Medicine, during the past year, I am afraid, the Federal Government's response is still woefully inadequate.

I might just say as an aside, I think that Senator Glenn's bill, the one about the right to know and the right to have full knowledge and informed consent before any experiments are done on you or you are involved in any experiments is really the right thing that we should do at this time.

As you mentioned, Madam Chair, I do have a somewhat personal interest in this, and I will tell you how I got involved. Last year, a little over a year and 4 months ago, my next oldest brother died, at a fairly young age, of thyroid cancer. And, of course, when he came down with it, I had already had thyroid problems of my own preceding that by a few years. I just thought that was quite unusual, and, when he came down with thyroid cancer, of course, it was considered not life-threatening. Usually, thyroid cancer is one of those that can be handled. But his had been detected way too late. It had already metastasized. He fought it valiantly for about, oh, I think going on almost 10 years and finally succumbed to it last year.

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[1] The prepared statement of Senator Harkin appears in the Appendix on page 6.

During that period of time, I began to look more and more at the incidence of thyroid problems in this country, and what I found was really alarming. I found, for example, Senator Glenn, about the use of Synthroid, which, as you know, takes the place of the thyroid hormones—I have been on Synthroid now for about 18 years. But the use of it over the last decade, decade and a half, has just shot up precipitously. I asked the question, either one of two things, either doctors are over-prescribing it or there is something going on out there. I don't think doctors are over-prescribing it. It doesn't seem to me like a highly profitable drug or anything like that, but doctors are detecting more and more thyroid problems. If you look at the chart on the use of Synthroid, it has just skyrocketed.

Well, that kind of alarmed me, and then what happened to my brother, and then I looked at how much research was being done on thyroid cancer. And, of course, since it is a slow-acting cancer and not too many people succumb to it—the survival rate is fairly high, More interest was focused on breast cancer, of course, and colon cancer and lung cancer, things like that. But I found out there just wasn't anything being done about thyroid cancer. So I began working through my capacity, with Senator Specter, on the Appropriations Committee and asking questions about the research into it.

Well, just about that time, this study lands in our lap, and you can imagine how startled I was to see the juxtaposition, of how these two things come together at the same time. And so I looked at the study and looked at the map, and, of course, what I saw startled me as much as it did you, Madam Chair, when I saw that Iowa, of all places, had a lot of radioactive hot spots.

I then began a process of talking to scientists and others and found out that when the nuclear explosions happened in Nevada, a lot of the Iodine–131 would get in the upper atmosphere, would float along through the jet stream, and then it would come down. It would come down at different places, so you would find a kind of patchwork across the country, and that is why you find some hot spots, for example, up in Maine.

The next thing I found out was that during the 1950's—and you might want to explore this a little further, again, for the basis of having some history on this. During the 1950's, Kodak, which is located up in Rochester, New York, had been noticing that some of the films that they were sending out were being clouded. Somebody figured out it always happened around the time of a nuclear test. So they got a hold of the AEC. The AEC agreed to warn them beforehand when they were going to conduct a nuclear test. Therefore, they would protect their film, and they wouldn't send it out. Then they would wait a while, and then send it out.

I thought, my gosh, if they could inform Kodak, why couldn't they inform the dairy farmers and the people that lived in my area and your area, places like that, to not drink the milk for a while or don't let the cows graze for a while on the grass. Iodine–131 does decay, and so you could—the half-life is not that long, so you could wait a while, given some information. So Kodak got the information. The American people didn't.

So all of this led me to think that we just really had to do something. I don't know why the study took so long. You will look into that. I would agree with you; from my perusal of it, I really do think the science is good. I have no quarrel with the science and what they did on this study. I just have a problem with the time and the release of the information.

Just a couple of other items I would mention to back up a little bit what you both said on the Iodine–131. A lot of these hot spots were identified as receiving 5 to 16 rads of Iodine–131. You ought to put that in perspective. The Federal standards for nuclear power plants require that protective action be taken for 15 rads.

To further understand the enormity of the potential exposure, they estimate 150 million curies of Iodine–131 were released by the aboveground nuclear weapons test, three times that from Chernobyl.

These hot spots, as you know, were all over the place, and as you said, Madam Chair, the most affected were children because their thyroids were smaller, they drank more milk. In my brother's case, he lived in Pennsylvania at the time, so they said, well, OK, here is someone who had thyroid cancer, but he didn't live in a hot spot. Well, he sure did when he was a kid. And that is what we drank, Senator Glenn. We drank cow's milk. And we didn't pasteurize it, either. We just put it through a cloth and drank it, and that was it in those days.

And so you look back, and you wonder how many people there are that have moved out of those areas or lived in those areas, maybe living in the cities, and have no idea that they were ever exposed to any of this.

So that is why, when I hear the NCI say that, on average, everyone is OK. I don't think this is one place where we can be satisfied with saying, well, the average is OK. We have got a lot of people out there who were exposed, and as you know, these things take a long time to develop. And if you look, again—I think—I am not on real solid ground on this, but I think the incidence of the use of Synthroid is affecting the age population about my age, 50's and early 60's, someplace in there, who were kids at that time, if you look at the incidence. I am trying to get a better handle on that, but my first look at it seems to be that that is so. So I think that we have a responsibility to get this information out and inform them of the risks.

Now, I have a problem—and I know you will look into this, and I hope you do—about the IOM saying that no screening should take place. I am concerned about that. I am not a doctor, but I do have a problem with this. I think it needs to be examined very closely. According to American Cancer Society information, the NCI is wrong to oppose screening. Why they are opposing it, I don't know. It just seems to me that they are saying, well, people will get excited and maybe they will do things that they don't have to do. And as I read some of the report, I was concerned about that attitude, that, well, people might go in and get check-ups or do things that they don't have to do.

And there is one part of the report I just drastically disagree with, and I don't have it right in front of me, but it was that you could wait; that it didn't make any difference how soon you detect thyroid cancer, you could wait a little bit later, it was not that big of a problem up front.

Well, I can tell you from my brother's experience that this is nonsense. Any cancer, the earlier you detect it, the earlier you take steps to control it, it means your survival rate is going to be increased by that much. So I just don't buy that, and I don't understand how they came up with that kind of a conclusion, that they didn't have to be worried about people coming in early, they could wait and just catch it during the normal course of getting physicals. But there are a lot of people out there without health insurance that don't come in for annual check-ups, and I will bet you there are a lot of times where you get annual check-ups, and they don't check your thyroid. I just wonder how many—mine was just caught. I was in the military. I have taken physicals every year of my life, and all of a sudden, 1 year I happened to take a physical, and the doctor just said, "There is something wrong with your throat." And it had been there before. I mean, it didn't just happen in 1 year. One doctor happened to catch it, and then with some MRIs, we were able to get a better handle on it.

But there are a lot of people out there who don't have health insurance. They don't come in for their annual physicals. And I believe information needs to be gotten out to these people and to say that if you lived in certain areas and you were a child, you ought to get in and have your thyroid checked. That is all I am saying.

Again, I am not here to condemn the scientists. I think that they have done a good job on the science, but I do think they did an inadequate job in responding to the human health consequences of the fallout exposure.

Again, we are dealing with real people. We are not dealing with just averages. We are dealing with people out there that need this kind of information. I think the medical community needs the information, too, and I think doctors who give physicals and our community health centers around the country ought to be given this information. That would be a massive flow of information from the government to consumers, to the health professionals, community health centers all over this country to make sure they check on the thyroids of people, ask them where they lived when they were kids. Ask them about the milk they consumed and things like that. And in that way, I think we can do a much better job and fulfill our responsibilities more adequately.

Madam Chair, if I could, I would just like to ask consent that a statement prepared by the Physicians for Social Responsibility who examined the issue be made a part of the record.[1]

Senator COLLINS. Without objection, it will be.

Senator HARKIN. And I thank you again for giving me this opportunity to testify. I would be glad to try to answer any questions if I can.

Senator COLLINS. Thank you very much for your testimony.

Senator Glenn, do you have any questions?

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[1] See Exhibit 4, which appears in the Appendix on page 746.

Senator GLENN. Just very short. You mentioned Chernobyl. That was interesting. I hadn't heard those figures before on comparison of our total fallout from that and Chernobyl, which brings up the international aspect of this whole thing and whether these things are all cumulative, wafting around the world on jet stream winds and coming down all over the place. I don't know whether you have looked into that any further as to whether when we were doing our testing, or other people were doing their testing, that we were monitoring or were able to monitor or even have any record of what the fallout was around the world in different places, whether it is the southern part of Africa or northern Russia or whatever. I don't have any idea what the answer would be.

Have you seen any studies on that?

Senator HARKIN. I haven't, Senator Glenn. I just asked my staff. They haven't seen any, either. And I would think Chernobyl being where it is located, and we know the jet stream goes from west to east, prevailing winds, you would probably have to look in that direction. But obviously some of that could have reached us, too.

Senator GLENN. You have a half-life on this iodine, of about 8 days. I don't know about the effects of Chernobyl—it may not have had that much effect on us here, but I think the overall—I am just thinking of the overall testing programs different nations had going back at that time.

I don't want to spend a lot of time on it. I am just curious about it. I hadn't really thought of that before.

Senator HARKIN. No, I hadn't—well, I had thought about Chernobyl. I just didn't know. But I don't know if any investigations have been done or not. But you are right about the half-life, and I think they need, what, something like 2 or 3 or 4 half-lifes before there is not any real problem.

Senator GLENN. The normal half-life is about 8 days, and it goes down from there?

Senator HARKIN. Yes, I think it is like 30 days total. After about 30 days, I think, something like that. You can ask the experts, but I think that it is something about that, where it just won't affect you any longer. But you are right, Chernobyl gets in the jet stream, 2 or 3 days it is here.

Senator GLENN. But that would take it out across not only what is now Russia, the old Soviet Union, but Japan, Korea, other nations of the Far East, maybe even winds down into India or places like that on occasion. It would be interesting to see whether anybody through the World Health Organization or anyone has done any studies of the overall effect of iodine and other fallout.

Senator HARKIN. You might ask the people—I don't know the answer to that question.

One other thing Senator Glenn, Senator Specter and I have put into the appropriations bill a provision that I would like to draw your attention to, to do some further studies on other radionuclides that were involved in those tests. We don't know about those, either. There are other radionuclides—cesium, of course, and we know about the strontium, plutonium, and we don't even have a handle on what happened to that kind of fallout.

Senator GLENN. Not to delay this, Madam Chair, I know we have a number of witnesses, but we did extensive studies on some of the downwinders out of Hanford, Washington, when some gases were released there that got into some of these other areas also. This Committee in particular has followed that through the years and done a lot of work in that area, too. So it all combined into a big picture. People need to know more information in a timely fashion just so they could have an annual screening if they were in a hot spot for example, or could watch out for symptoms in their children.

Thank you, Madam Chair.

Senator COLLINS. Thank you, Senator Glenn. Thank you, Senator Harkin.

Senator HARKIN. Again, thank you, Madam Chair, for conducting this hearing. It is vitally important.

Senator COLLINS. Our next panel of witnesses consists of Dr. Owen Hoffman and Dr. Barry Johnson, who will testify about the significance of the NCI's findings on the radiation resulting from nuclear weapons testing.

Dr. Hoffman, a scientist who served as a consultant to the NCI study, is currently president of SENES Oak Ridge, Inc. in Tennessee. Dr. Johnson is the Assistant Administrator of the Agency for Toxic Substances and Disease Registry. That agency is part of the Department of Health and Human Services and is responsible for conducting medical studies, registries and monitoring.

Pursuant to Rule 6 of the Subcommittee, now that you all are comfortably seated, I would ask that you stand and be sworn in.

Please, raise your right hand. Do you swear that the testimony that you are about to give is the truth, the whole truth and nothing but the truth, so help you, God?

Dr. HOFFMAN. I do.

Dr. JOHNSON. I do.

Senator COLLINS. Dr. Johnson and Dr. Hoffman, there is a third person at the panel. Could you, for the record, identify him, please?

Dr. JOHNSON. Madam Chair, I am accompanied today by Dr. Jeffrey Lybarger, who is the Director of our Agency's Division of Health Studies.

I may refer to him on issues of technical issues, if that arises during the testimony.

Senator COLLINS. Thank you. We look forward to hearing from each of you today. Your written testimony will be made a part of the record but in order to allow ample time for questions and answers, we are going to limit your oral testimony to about 10 minutes each.

We are going to be using a timing system this morning. You will see right in front of you three lights. The green light will signify the beginning of your 10-minute period. About 1 minute before the 10-minute period is through, it will turn to yellow, which will encourage you to wrap up your testimony and make your final points.

But I do want to emphasize that your entire prepared testimony will be in the record.

Dr. Hoffman, we will start with you this morning.

TESTIMONY OF F. OWEN HOFFMAN, PH.D.,[1] PRESIDENT AND DIRECTOR, SENES OAK RIDGE, INC., CENTER FOR RISK ANALYSIS, AND CONSULTANT TO THE NATIONAL CANCER INSTITUTE'S STUDY, OAK RIDGE, TENNESSEE

Dr. HOFFMAN. Thank you, Madam Chairman.

The Subcommittee has requested that I testify today about two primary issues. The first being my views on the overall health impact to the American people from atmospheric testing of nuclear weapons at the Nevada test site, and the second being my personal involvement with and observations about the overall production of the National Cancer Institute's report, its conduct of research on the topic and including an interpretation of the results of the National Cancer Institute's Iodine–131 study.

My professional training is as an environmental scientist. I have more than 25 years of experience in the field of environmental radioactivity. During my career, I have devoted considerable effort to the study of the environmental transport and health consequences of Iodine–131 and other radionuclides.

In 1987, I performed experimental research for the National Cancer Institute to produce information that helped confirm some of the assumptions that were made in this study. I also served over a period of years as an unfunded consultant to advise on methods for the analysis of uncertainty in the National Cancer Institute's dose estimates.

I would like to also point out that I have served as chief scientist to the International Atomic Energy Commission on the use of Chernobyl data to actually test the accuracy of environmental models and, indeed, the Chernobyl fallout went around the world. We even measured it here in the United States.

What are the most important findings of the National Cancer Institute's report? I would like to point out that it makes comprehensive estimates of the thyroid dose resulting from each of 100 atmospheric tests held in Nevada during the 1950's. In all, approximately 150 million curies—not 116—but 150 million curies of Iodine–131 was released to the atmosphere from the Nevada test site. Now, this is about 3 to 4 times the amount released from Chernobyl. You had an earlier estimate of that release. I would like to correct it. It is 45 million curies, not 7 million curies of Iodine–131 that was released from Chernobyl.

The National Cancer Institute report estimates doses of radioactive iodine that was received by individuals of various ages and who consumed various dietary sources of fresh milk for over 3,000 counties in the Continental United States. Let me make this point and let me make it clearly, that this is the largest and most extensive dose reconstruction ever carried out in the United States. Presently, there are dose reconstructions ongoing at Fernald, Ohio, at Hanford, Washington, at Oak Ridge, Tennessee, at Savannah River, Georgia, and at Rocky Flats, Colorado. Compared to all of these sites, the NCI dose reconstructions is the big one.

Iodine–131, as mentioned previously, is one of many radionuclides released in fallout. It is because of its affinity to rapidly deposit on vegetation and to be accumulated into food chains, especially the milk food chain, and then to affect the thyroids of children, is why it gets so much attention. Iodine–131 is not the only radionuclide in fallout; however, the NCI study was mandated by Congress to focus only on Iodine–131.

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[1] The prepared statement of Dr. Hoffman appears in the Appendix on page 48.

The other thing I would like to mention is that the plumes from the Nevada Test Site went beyond the borders of the United States. The NCI study, however, was restricted to just the doses to the American people and, as far as I know, the overall effects of the Nevada Test Site fallout in our neighboring countries has not been assessed.

The primary population at risk would be those in childhood at time of exposure. It was mentioned previously that the plumes went throughout the United States. It has also been mentioned previously that an initial estimate of health risk ranged from 11,000 to 212,000 excess cases of cancer. I would like to point out that those estimates would primarily be manifested in children, who were under the age of five at time of exposure and who are primarily females. And the majority of those cases would occur for people living in the Midwest and Eastern United States because that is where the population is.

So, even though the so-called hot spots appear to occur in the West, the population base is rather small so the overall cases of cancer that was manifested in the West would be small compared to the consequences that would have occurred in the eastern United States.

For children born in 1952 and for children consuming either above-average quantities of commercial milk or unpasteurized milk from local sources, such as a family cow, backyard cow or a local farm, the National Cancer Institute estimates that there are approximately 270 counties in the United States where the median or central estimates of thyroid doses would have reached above 30 rads and nearly 2,500 counties where the central estimates of dose would be between 10 and 30 rads.

Those dose estimates well exceed any past or current radiation protection guides dealing with maximum dose limits to the thyroid. They also exceed emergency reference levels, which are recommendations for taking action, either recommending that cows not be fed fresh feed or banning milk from the market.

The World Health Organization currently is recommending that at doses that can be averted as high as 1 rad, that stable iodine tablets be distributed in order to block thyroid uptake of radioactive iodine. The current recommendations of the Food and Drug Administration and the EPA recommends this procedure at 25 rad. So, these dose estimates from exposure to NTS fallout approach and exceed emergency levels for those who were in childhood at time of testing who were consuming above-average amounts of milk or milk from local sources.

Another measure of comparison is looking at risk limits for Superfund sites. Now, at Superfund sites the need to clean up is triggered when risks are in the range of 1 chance in a million lifetime health risk of cancer up to 1 chance in 10,000 for maximally-exposed individuals. Usually when it exceeds 1 chance in 10,000, the need for clean up is taken seriously.

I would like to point out that for children under the age of 15, a life-time risk that would approach or exceed 1 chance in 10,000 of an excess risk of thyroid cancer would be on the order of just 1 to 2 rad. And the risk would increase in a multiplicative fashion for every rad increase beyond that.

So, that concludes a brief summary of the significance of the study. Now, another question that I have been asked to answer is, have the important findings and their significance been adequately conveyed to the public by the NCI? To answer this, I offer to you an opinion. The information in the report is extensive. It is of the highest technical quality. There have been numerous presentations made in the past to scientific committees but, I would contend that, no, the information is not readily accessible to people who are non-technically trained and who have an interest in this topic.

And the reason for this is that the executive summary of the report focuses mainly on average doses. The average dose is controlled by the majority of the population who were adults at time of exposure and the risk to those individuals is very small. The risk to the U.S. population is controlled by those who were in very young childhood and who were consuming large amounts of milk.

One has to go into the appendices of the report, into Section 8, and start combing through the maps in the back of the report before one obtains a full appreciation as to how high these doses could have been. And, in fact, if one really is interested in discerning how high the doses could have been, it is necessary to get into the NCI web site and actually begin to put in information about dietary habits and date of birth in order to get quantitative information that would be pertinent to the interest of any individual.

Now, I would like to just finish with a personal recommendation. That is I think we would not be here today if the National Cancer Institute had adopted the same commitment to openness and public involvement as is now the standard practice in dose reconstruction studies that are currently taking place throughout the United States. Those studies are being conducted by the Centers for Disease Control and by various State Departments of Health.

Had there been public outreach and a commitment to openness, I do not think the NCI report could have been delayed, and I think that the report would have been consistent with its full mandate; which is: To include estimates of health risk. I think one of the main reasons why it is difficult for members of the public to understand the information in the NCI report is because, contrary to the Congressional mandate given in 1983, there are no estimates of health risk.

It is not like openness is anything new. Members of NCI and I have had these discussions at least over the last 8 years, but it is only recently as a result of, I would say, tremendous media pressure as of last summer that the report was published. Since publication, however, there has been, as far as I can see, every attempt made by NCI to answer all questions posed to it.

That concludes my presentation, and I am happy to answer any specific questions that you have.

Senator COLLINS. Thank you very much, Dr. Hoffman.

Dr. Johnson.

TESTIMONY OF BARRY L. JOHNSON, PH.D.,[1] ASSISTANT SURGEON GENERAL, ASSISTANT ADMINISTRATOR, AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY JEFFREY LYBARGER, M.D., DIRECTOR, DIVISION OF HEALTH STUDIES

Dr. JOHNSON. Madam Chair, Senator Glenn, good morning. I am the Assistant Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR). I am accompanied today by Dr. Jeffrey Lybarger, Director of our Division of Health Studies.

At the request of the Subcommittee, our testimony today will address ATSDR's medical monitoring responsibilities under the Comprehensive Environmental Response Compensation and Liability Act known as CERCLA or Superfund.

In particular, we will describe ATSDR's finding that medical monitoring of persons exposed to radioactive iodine released in the past from the Hanford Nuclear facility in Richland, Washington, is called for under CERCLA. Our testimony also relates the public health approach taken by ATSDR in considering CERCLA's medical monitoring provisions when populations have been exposed to hazardous substances released into the environment.

Further, at the Subcommittee's request because the Institute of Medicine recently recommended against thyroid cancer screening, we will highlight our differences in decision making and why we continue to support our decision for a medical monitoring program for a sub-population of well-defined persons exposed as children to Iodine–131 released from the Hanford facility.

ATSDR interprets its CERCLA language on medical monitoring as an important public health intervention that provides early diagnostic and referral services for a well-defined population's health risks.

Early detection of a change in health status is the most effective way to lessen the burden of more advanced disease and enhances survival. ATSDR's public health approach for considering a population for medical monitoring involves a rigorous process that applies established medical monitoring criteria for a specific site, using a multidisciplinary panel of experts to apply and assess the criteria, assures independent and external peer review on all matters of science, that will support an involvement of affected stakeholders certainly including the affected public, reviews risks and benefits as part of a formal agency approval process, implements medical monitoring activities when indicated, and periodically evaluates the medical monitoring program for effectiveness and quality.

In 1995, ATSDR commenced a deliberative process to determine if medical monitoring was warranted for persons at increased risk of thyroid cancer and other conditions from exposure to Iodine–131 released from the Hanford Nuclear Reservation during the period 1945 through 1951. A dose reconstruction study had documented large releases of Iodine–131 into the atmosphere and provided dose estimates of representative individuals according to their age, and where and when they lived, within a large geographic area surrounding Hanford.

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[1] The prepared statement of Dr. Johnson appears in the Appendix on page 61.

From these data, ATSDR determined that the major public health risk is among young children downwind of the facility who consumed Iodine–131 contaminated milk during the period 1945 through 1951. Early in our efforts, ATSDR and CDC jointly formed the Hanford Health Effects Subcommittee to advise the agencies on their research and public health activities related to the Hanford facility. This committee comprises of 21 persons who represent community, business, government and other interests. Our meetings are held on a quarterly basis, in public, and generate considerable media attention that further promotes public awareness and education.

We also work closely with the Intertribal Council on Hanford Health Projects which includes representation from nine tribal nations in the Hanford region. The HHES, the Subcommittee which I referred to, provides an essential resource for expressing health concerns from communities and tribal nations. This committee reviewed ATSDR's approach to and findings from the consideration of the medical monitoring program.

In consultation with an expert panel, we determined that a median 10 rad or higher thyroid dose for children would place these individuals at significant increased risk of thyroid disease as adults. This was based on the extensive medical literature of external radiation exposures that support elevated thyroid cancer risk at this dose level or higher among children. These elevated thyroid cancer risks occur for many decades following radiation exposures to the head and neck in children.

Moreover, there is an increasing amount of medical literature that supports a reasonable association between radioactive iodine exposures and excess occurrences of thyroid neoplasms. This literature includes published studies of populations exposed to the Chernobyl fire in 1986, Marshall Islanders exposed to the 1954 BRAVO test releases, school children exposed to the Nevada Test Site atmospheric testing releases during the period 1951 through 1962, and preliminary findings from the Hanford Thyroid Disease study.

Our analysis estimates that 14,000 people, the majority of whom were exposed in 1945, would have received a sufficient thyroid dose of Iodine–131 as children to place them at significant risk of thyroid cancer and other thyroid and parathyroid conditions. Because there is no randomized controlled study proving the benefits of thyroid cancer screening, ATSDR conducted a prevention effectiveness analysis to project the potential harms and benefits of a program based on a clinical decision model. The prevention effectiveness analysis also allowed us to project which benefits and which harms might result from various medical monitoring scenarios.

Clearly, a well-defined high-risk population must be identified for a program with thyroid evaluation to derive the most benefit. The geographic precision of the radiation dose estimates from the Hanford releases was a key in ATSDR's prevention effectiveness analysis and helped clearly define the at-risk target population. As I indicated 14,000 people we estimate.

Again, the Hanford Health Effects Subcommittee was a very valuable resource for discussing risks and benefits attending medical monitoring for thyroid disease. After 18 months of careful consideration and analysis following meetings with executive and senior scientific staff and a meeting with community and tribal representatives, Dr. David Satcher, as a former ATSDR administrator, and Director of the CDC, signed the decision memo for medical monitoring on February 7, 1997.

Now, differences in decision making between ATSDR and the IOM report. First, ATSDR is directed under CERCLA medical monitoring programs for populations at significant risk of adverse health effects from exposure to hazardous substances. This represents a different type of public health activity, we believe, in the setting of a national policy or standards for thyroid cancer screening.

Second, we perform our work on a site-specific basis using the best available scientific and medical information and following a rigorous process that is based on our seven criteria for medical monitoring. We not only involve the affected public in our decision making process, but also conduct external scientific peer review of our work to make the best public health decision possible.

By consulting recognized experts on the medical issue under consideration and involving the public most directly affected by the proposed intervention, our process provides an important and necessary balance for public health decision making.

Third, because we are not setting national screening policy, our criteria do not require a randomized control study showing the benefits of screening, although, we would certainly use such data if available.

Fourth, we agree with IOM that the current dose estimates for U.S. counties have large uncertainties which makes it difficult to readily determine who is at highest risk. At Hanford, however, we are fortunate that the dose reconstruction study estimated doses at a much more precise level of geographic resolution: Specifically 6-mile-by-6-mile areas.

In closing, ATSDR considers medical monitoring of a well-defined, high-risk population to be consistent with the central principle of public health: Prevention of disease as preferable to treatment and medical care, and early loss of life. Moreover, for maximum effectiveness, prevention efforts must involve the public that will be impacted by these public health decisions and efforts.

Thank you.

Senator COLLINS. Thank you, Dr. Johnson.

I am just going to have a couple of brief questions for Dr. Hoffman before turning over the questioning to Senator Glenn, since this is a Minority investigation.

Dr. Hoffman, as I mentioned in my opening statement, one of the most important findings of the NCI study in my view is the fact that contrary to what one might think the fallout from these nuclear weapon tests was not limited to areas very close to the Nevada Test Site. And you mentioned specifically the Northeast and the impact on people born in 1952, which was the year I was born. So, this is of some personal interest to me.

I would like to, just briefly, illustrate the effect of the prevailing winds, look at my home State of Maine. There is a chart of the entire United States that I believe is part of the National Cancer Institute study,[1] part of the report that shows Aroostook County, Maine, where I grew up, as being a particular hot-spot where people were exposed to 30-plus rads. So, a very high exposure rates. But our charts take a different point. They start with January 1.

And what I would like to do, to just illustrate the point that you can live very far from where these tests were conducted and still there is a significant impact, is have you walk us through the charts. The first chart[2] relates to those consumers, primarily children—I assume we are talking about—who consume an average amount of milk. I would add that I feel like I finally won many years later the battle with my mother on drinking milk, but small consolation.

Dr. Hoffman, would you walk us through these charts?

Dr. HOFFMAN. Yes. What you have here is an excerpt of the results that you would find in the appendix of the National Cancer Institute's report of October 1997. And what this chart shows is that virtually the entire State of Maine would have received doses in excess of 3 rads for children who were consuming just an average amount of milk and who were born on January 1, 1952, with the exception of a few counties, one county right in the center of Maine. You know the name of the county, I do not.

Senator COLLINS. It is Penobscot and Piscataquis Counties.

Dr. HOFFMAN. Yes. Where the doses would be in the category of 10-to-30 rad for such an individual.

Senator COLLINS. I would next like to look at a second chart[2] which relates to consumers who drank a great deal of milk and the impact changes rather dramatically in this case, it looks like to me. But, again, if you could help us understand it.

Dr. HOFFMAN. I think that this demonstrates one of the strengths of the calculations that have been made in the National Cancer Institute's report. In their report they did consider the fact that some children would consume much more milk than just the average. And, so, they targeted a calculation for individuals that would be consuming more than just the average amount. And for those you see the doses increase quite a bit. Now, in this second chart almost the entire State of Maine is impacted with doses ranging from 10-to-30 rad.

Senator COLLINS. And the third chart[2] I want to show you illustrates those who drank a great deal of milk from what we call a backyard cow. It could be someone living on a farm, for example. Could you comment on this chart?

Dr. HOFFMAN. Yes. The reason why the backyard cow is important is that there is no dilution from milk transported from outside the region. Also, backyard cows tend to produce less milk on the total and have the potential for transferring more iodine into their milk than the commercial dairy cow.

And in this circumstance, for people who either are consuming milk from a backyard cow or a local farm, the entire State of Maine (for individuals born on January 1, 1952), would have received doses between 10-and-30 rad.

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[1] See Exhibit 1a, which is retained in the files of the Subcommittee.

[2] See Exhibit 1b, which appear in the Appendix on pages 90–92.

Senator COLLINS. Thank you for that explanation of these charts. Just one follow-up question. It occurs to me as I listen to Senator Harkin recommending that there be widespread screening and then when I read the report recommending that there not be widespread screening that perhaps there is a middle ground here.

And that is that if this material were communicated to physicians in, for example, the State of Maine, who may not be aware of the risk factors and the exposure that occurred during the 10-year period in question, that perhaps physicians armed with that information could decide whether testing or screening was appropriate for their patients. But if they do not have access to this kind of information or they are just not aware of it, they cannot make those kinds of judgments.

Do you know—and I will ask the NCI officials this question—but has there been an effort to educate the medical profession about the rather startling and unexpected findings on the dosages of radiation received during those periods?

Dr. HOFFMAN. I am not aware of a major educational effort at this time. I believe at the time of the release of the information that one of the members of the National Cancer Institute's Advisory Committee, Dr. David Becker, indeed on his own, attempted to educate and make contact with the American Thyroid Institute in order to caution the medical community about the potential hazards of massive screening.

This is not to be taken lightly. Screening, if applied without due caution, can result in more harm than good.

Senator COLLINS. And I agree with that and I am not advocating frightening the public into thinking that we need a massive screening program. But on the other hand, it seems to me that physicians in Maine, for example, treating people my age and a bit older who grew up during this period in areas that are hot spots, should have this information so that they can decide on a case-by-case basis whether or not screening might be appropriate.

Dr. HOFFMAN. Well, I would like to mention that in my own analysis of the data, I do not see as much evidence for hot spots as I see evidence for age at time of exposure, gender, and especially for those individuals, those rare individuals on a diet of goat milk, to determine the high-end exposed group.

That group will be at more risk than any average group that might be associated with a particular geographical location.

Senator COLLINS. Thank you, Dr. Hoffman.

Senator Glenn.

Senator GLENN. Thank you.

What is the difference between a backyard cow and a dairy cow as far as radiation goes? I do not understand why that would be different?

Dr. HOFFMAN. Well, dairy cows are managed for maximum production of milk and they are often given a much higher percentage of concentrates, they may produce upwards of 30 quarts of milk or about 7 gallons of milk a day; whereby a family cow that is set out to pasture to graze may only produce from one-third to one-half of that.

Senator GLENN. In other words, your dairy cow would get more supplemental feed that would not be raw grass and things like that that are often more exposed to fallout?

Dr. HOFFMAN. That is correct. And also because of the type of cows usually used for family use are low producers, there is a tendency for them to concentrate more iodine into the milk than those cows, like the large Holsteins, that are used for commercial diary operations.

Senator GLENN. Dr. Johnson, am I correct to say that you do not recommend any overall screening now? Would you go along with screening in some of these hot spots where we have seen a lot of thyroid cancers develop? Or do we have enough information to do that?

Dr. JOHNSON. Senator, you are asking me to comment on the National Cancer Institute study of which I am not that knowledgeable. What ATSDR did with regard to a comparable situation where Iodine–131 was released from the Hanford facility, we do recommend medical monitoring or, if you wish to call it, screening. And that is for persons whom we estimate to have had 10 rads or above exposure, primarily 1945–1951. Of that 14,000 people, some 60 percent have had exposure to 25 rads or greater. So, we have recommended under Superfund that medical monitoring be done for that group of 14,000 people.

Senator GLENN. In your studies, when you are reviewing the studies did ATSDR take specific steps to involve and inform the public and what specific steps did you do?

What I am looking for really is this also: What do we do once we put this out to the public? What does the public do with it? We do not want openness just for openness' sake and say all wash your hands, everything is great, now, we have protected the public. The public has to be given this information in some way that means something to them or it is sort of academic whether we put it out there or not.

What did you do to help people get informed on this and to take precautions in their own families some way or was there an effort like that? If so, describe it.

Dr. JOHNSON. I think I would like to begin, sir, by indicating that the practice of public health for quite some time has involved involvement of communities and tribal nations and getting the public involved is now very much a part of the fabric of public health.

With regard to what we did specifically at Hanford, as I said in my testimony, we and CDC, jointly, created something called the Hanford Health Effects Subcommittee. Twenty-one persons representing a broad representation of the community around Hanford. State health departments, the business community, concerned citizens, etc.

We began our effort to determine if medical monitoring for the Hanford facility should be pursued by discussing that with this committee that we formed. The committee for 2 years met quarterly. They provided us with information on their health concerns, advice on various issues of community education.

Through that committee we were able to outreach to State and local health departments on what we felt were the issues related to Iodine–131 released from Hanford. We came to a deliberative decision under Superfund that medical monitoring should be pursued and that was done in conjunction with this committee, with the media.

And we have tried to educate health care providers, principally through working with State and local health departments.

Senator GLENN. Is there any natural occurring Iodine–131 in nature? Does it all come from this? Is there any at all from lightening or whatever? Is there any natural Iodine–131?

Dr. HOFFMAN. It is a product of nuclear fission.

Senator GLENN. Yes.

Dr. HOFFMAN. And, so, to the extent that in the past there have been natural nuclear incidents of spontaneous fission, that would be the source of materially-occuring Iodine–131. But because of its short half-life of 8 days, it would not persist.

Senator GLENN. One of the things Congress requested was that a risk assessment be done by the report, but I do not think any was included in the report.

I understand that National Cancer Institute did a risk assessment in 1997 and put it out in a press release. I do not know what the extent of that was or what the details were that went out. I guess we could say that was some effort at making this information available to the public.

I do not know how extensive that was. But how difficult is a risk assessment to do? Should that be a natural outcome of this kind of a study?

Dr. HOFFMAN. I believe it should. Today in the dose reconstructions that are ongoing at Hanford, Rocky Flats, Oak Ridge and Fernald, the end point of the study is an estimate of individual risk.

And, so, it was personally surprising to me that risk was not aggressively pursued in the National Cancer Institute study. The National Academy of Sciences and the Institute of Medicine report conclusively state that there is a causative link between Iodine–131 and thyroid cancer. This information has been reinforced from the experience of the follow-up of children exposed from Chernobyl. Yet the very people who are most intimately involved in the study of children exposed to Chernobyl fallout are the same people involved in the National Cancer Institute's Iodine–131 report. So, I do not know why information about health risk was not included.

Senator GLENN. Yes. We are making a major issue of openness, as we should, but what happens then when we are open? Let us say all the information has been put out, what would the State health departments or doctors or AMA, whoever, what would they do?

Is it just a general awareness through the medical industry that they ought to be more careful in screening this or is there an antidote to this in any way or any protection people can take?

In other words, openness just for openness' sake is one thing, but openness to get information out there that people will act on and are concerned about, that is very constructive. How do we make this effective?

Dr. HOFFMAN. Well, yes, you have stated exactly the point that I was trying to make. Through openness, the community with a need for the information is informed at the earliest stage of the project and they have time then to digest the information and take appropriate action.

The information about the high thyroid doses throughout the United States, that information perhaps was known as early as 1965. But in the National Cancer Institute report the first preliminary results were available in the late 1980's. In an open study that preliminary information would be made available and people would have had the opportunity to respond to this information.

Senator GLENN. Do you have any reason that you know of why this was not put out earlier? Was it just a delay or other things that people were involved with do you know?

Dr. HOFFMAN. In my personal opinion, I think it is in part a reflection of the traditional scientific process of not releasing information until it is absolutely final. And because the information was not absolutely final it was not released.

But contrary to that scientific tradition, present-day public health dose reconstructions will release draft results at an early stage with the understanding that it is draft information and subject to change.

Senator GLENN. I think you had indicated, maybe in your longer written statement or earlier, that you believe the data was completed about 1989 and the report was completed about 1992. That is 8 and 5 years before the report was issued. Do you know why that occurred?

Dr. HOFFMAN. Well, I would like to just make a correction. I do not know if the report was completed in 1992 but I think the calculations were finalized about that time. So, the basic information was well in hand in that time period.

Why did it take from 1992 until the present time to release the report? I think, you must put that question to the authors of the report.

Senator GLENN. From a practical standpoint, is there any easy test for thyroid cancer? If I was concerned about a child or a grandchild that had thyroid cancer, is there anything except the doctor finding lumps or do you have to go through the expensive things like an MRI and things like that to determine if there is a problem there? There is no easy test, is there?

Dr. JOHNSON. Senator, the proposal we made that is specific to Hanford is a phased approach where a person would be seen by a physician who knows the issues, that is to say, radiation and thyroid disease. The first phase of that screening would involve palpation of the thyroid, a physical exam, a personal history and so forth.

The second phase of that effort would go into a program of ultrasound if referred into the second phase from the first phase. The third phase would be fine-needle aspiration where a small amount of tissue from the thyroid gland is examined for abnormal pathology.

Our program would then recommend under conditions that knowledgeable physicians then make the decision on whether or not to proceed with surgery or some other kind of more invasive procedures.

So, we see it as a phased diagnosis.

If I could comment also with regard to physicians. Our work with State health departments leads to work with local health departments, that leads to work with local medical societies, that leads to work with local health care providers. And it is a process that has to involve all those links—State, local, medical societies, local health care providers. Physicians are not well versed on issues of toxicology, radiation biology and so forth. And I do not think the public should expect that that should be the case.

Our responsibility is to provide that technical assistance and to provide other information that would be helpful in their practice of medicine.

Senator GLENN. Well, but you still depend on what? On things like AMA publications or do you have a report that you put out to every registered doctor in the United States?

Dr. JOHNSON. Again, we work under Superfund. It is a site-specific individual issue. For example, we recently had concern about PCBs and fish tissue. We worked with the USEPA to outreach to every physician in one particular State in the Midwest. It is not Ohio, sir. It was one of the other States. So, it depends upon the issue.

Senator COLLINS. Senator Glenn, I can yield the remainder of my time to you or we could go to Senator Durbin?

Senator GLENN. I yield to Senator Durbin.

Senator COLLINS. Senator Durbin.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thank you, Madam Chair.

I appreciate this hearing and I am learning a lot in a hurry about a subject that I do not profess to have any particular expertise. I am trying to really translate this into what I might expect the average person in my home State of Illinois to ask me if they should hear about this hearing and this report. Particularly when I look at one of the charts—and I am not sure you have them for all the States there, but you have provided them for us in the testimony—and I find that one of the communities near where I live, Christian County, Taylorville area, supposedly had exposures of greater than 30 rads of Iodine–131 thyroid doses for persons born on January 1, 1952, the backyard cow example.

What am I to tell someone who heard that, that this was the case? What kind of precaution or concern should they have over that fact, if they lived in that area in that period of time?

Dr. JOHNSON. Well, Senator, again, my agency is involved with releases of Iodine–131 from the Hanford facility so our work is not specific to the National Cancer Institute study, although there are parallel issues.

What we have said to the public that was exposed as children to Iodine–131 releases working through the media—working through the States of Washington's, Idaho's, and Oregon's health departments—that exposure does increase their risk for certain kinds of thyroid disease.

We have said that we believe this is a matter between persons and their health care providers and their physicians and that we are trying to provide that would outreach to those persons at elevated risk to bring them in for a kind of screening program.

Senator DURBIN. Is there a normal period of time within which you could expect this thyroid cancer to exhibit itself? If a person said, OK, I was living at Taylorville, I grew up there, I was a kid born in 1952, I am 46 years old, I have never had a problem, does that mean I am out of the woods when it comes to this particular concern? Or is it, no, you have just reached an age where it might be a particular concern?

Can you tell me that?

Dr. JOHNSON. I would like to refer that to my colleague, Dr. Lybarger, who is a medical doctor.

Dr. LYBARGER. Senator, the risk increases throughout one's lifetime to a general level of around 40 years. It does not decrease after that period of time. So, generally, it is a life-long risk of extra cancer.

Senator DURBIN. Can I ask you about some other things, too. Dr. Hoffman testified that Iodine–131 is just one of the radionuclides—I hope I am pronouncing that correctly—that occurs in fallout, but it is the one that has been the subject of the largest dose reconstruction study.

Are there other dose reconstructions of other radionuclides that ought to be conducted?

Dr. HOFFMAN. I believe so. There have been assessments of the impact of all the radionuclides in global fallout from the United Nations Scientific Committee on the Effects of Atomic Radiation. But a detailed assessment on the level of the National Cancer Institute's report for other radionuclides, beyond those communities immediately downwind of the Nevada Test Site, has never been done.

Also, there has not been an attempt, as far as I know, to estimate the individual risk associated with exposure to those radionuclides. Now, what I think is important, and the reason I would support such studies, is because the types of cancers and disease induced by exposure to those other radionuclides are more likely to result in a fatality rather than just a morbidity.

In the case of thyroid cancer mortality is less than 10 percent. The leathality fraction, or the chance of death, is much higher for the types of cancer induced by the other radionuclides.

Senator DURBIN. I do not want to over-state what you have just said so I want to make sure it is clear for the record. You are suggesting that this study with Iodine–131 indicates what probably occurred as a result of the fallout from the tests in creating a medical condition which is serious but not as life-threatening as some other cancers.

And you are saying that there are other radionuclides that might have come from these tests which should also be surveyed because of the potential danger which might be even greater than the danger of thyroid cancer, is that correct?

Dr. HOFFMAN. That is correct. But I would say that there are other radionuclides that did come from these tests, not might have, they did. And I personally have asked this question of the National Cancer Institute in the past and that is, why was there no attempt to expand the scope of the study? I feel the intent of that public law back in 1983 was to look at the full potential health impact of weapons testing at Nevada. To do that, you have got to look at all the radionuclides.

Now, the techniques that were developed to estimate Iodine–131 are the same techniques that could have been used to estimate all of the other radionuclides. So, the step to include an estimate for the other radionuclides in fallout was not a major step.

Senator DURBIN. What are the other radionuclides? Can you tell me? Is the list too long?

Dr. HOFFMAN. The other ones are Cesium–137, that has a 30-year half-life and is readily taken up in the food chains; Strontium–90, that acts very much like calcium and is taken up like iodine into milk and can deposit in bones. Over the long-term, radioactive Carbon–14, which also will be prevalent in human foods. Those three radionuclides can be measured even today.

However, the bulk of what can be measured was contributed by global fallout, not by Nevada Test Site operations.

Senator DURBIN. Can we use the same—let me see if I state this correctly—I take it what you have given us in this portrayal here and map, as Senator Collins and others have noted, is an indication of where these deposits of Iodine–131 were the most serious or the greatest. Can we conclude that these other radionuclides were likely to have been deposited in the same places?

Dr. HOFFMAN. Yes.

Senator DURBIN. We can.

Dr. HOFFMAN. Yes.

Senator DURBIN. Well, then I think what—I do not want to overstate this—but I think what we are considering today is the canary in the cage in the coal mine and it is looking very sick because of Iodine–131 and something worse may be out there. And I am afraid that—and I do not want to over-state this because this is a serious matter of public health and I do not want to cause great alarm—but if I follow your questioning, we need to get on this quickly.

We cannot allow the kind of delay and procedure that was used in this report to prevail again, so, that we can address these other radionuclides which are even more dangerous, which could have been deposited from this fallout or from some other source. Have I stated this correctly? Please, correct me if I am wrong because I do not want to be wrong.

Dr. HOFFMAN. I would not want to, at this time, make a statement about the overall effect until such studies had been completed. I would want to emphasize, however, that the health outcomes associated with exposures to these other radionuclides are more than likely to lead to the types of cancer that could result in a mortality. But whether we are dealing with a few thousand cases of excess mortalities or a few tens of thousands of cases of excess mortality I will not know until such studies have been conducted.

Senator DURBIN. Well, the reason I pointed out Christian County, Illinois, is that they have had a lawsuit recently concluded where there was an extraordinary incidence of a rare cancer, neuroblastoma, in four children and unexplained. And I do not suggest it has any connection here, but I can tell you that that has caused everyone in this area to be overly sensitive as to whether or not there is something unusual in that particular area and it just jumped right off the map when I opened up this chart and saw that this was one of the counties involved here.

I thank you, Madam Chairman.

Senator COLLINS. Thank you.

Senator Glenn.

Senator GLENN. Yes. Just one more follow-up one on Senator Durbin's comments. I was talking to the staff here while he was commenting. I believe you have strontium and cesium, also in the radionuclide family that are fallouts from some of this, too. Now, should we be concerned about some of those dosages because strontium, as I understand it, concentrates in the bones. It can cause cancer. Now, maybe it comes from some other sources also, I do not know. Cesium is more long-lived, I am told, and, so, you may have radiation in you from a collection of cesium over time.

Now, some of these things also are used in the medical profession for diagnosis as well as therapy for certain things. So, they are used in a controlled fashion that way. My question is, do you know whether you could give us some advice on whether the dosages are high enough from some of this fallout of these other radionuclides that we should be alarmed about them and should be doing some similar studies that cover these other areas? Or are they so rare that those other radionuclides, strontium and cesium, as a source of potential cancer is not large enough that we need to worry about it that much; there are other things that we should be concentrating our efforts on? Do you have any comment on that?

Dr. HOFFMAN. It is hard to come up with a simple answer to the question that you just posed. In order to give full public disclosure as to what the potential health impacts have been from testing at the Nevada Test Site, yes, I believe that investigations should be undertaken of the full suite of radionuclides that have been produced.

Have significant exposures occurred as a result of the deposition of these other radionuclides in fallout? I do not know the answer to this until such studies have been undertaken.

How significant is it likely to be? I think it is fairly evident that the highest exposures to these other radionuclides more likely than not to have come from global fallout because these are long-lived radionuclides that accumulate in the upper atmosphere and they can deposit over a number of years.

So, that what we currently measure in our foods and in soils of cesium, strontium, and Carbon–14, the bulk of that came in from global fallout and not from the Nevada Test Site. However, a fraction of that is still a contribution from operations in Nevada.

Senator GLENN. But do we have good information about what kinds of cancer or whether cancer is caused by these other things like the strontium and the cesium and others, as well as Iodine–131?

Dr. HOFFMAN. Well, for Iodine–131 the primary organ of interest is the thyroid and other than non-neoplastic thyroiditis the main issue of concern is the production of radiogenic thyroid nodules and carcinomas. For the other radionuclides, it is basically looking at the overall interaction of radiation in biological matter. And there, I believe, the scientific evidence is fairly conclusive and that is that any excess exposure to radiation increases one's risk over one's lifetime of cancer. That risk may be small but the risk is still there.

Senator GLENN. All right, but the fallout we received such as in Maine and the other places where there are hot-spots—it would be your opinion, I gather from what you said about the long-lasting life of this as opposed to the half-life—that these would not necessarily, strontium, cesium, problems, whatever they resulted in, would not necessarily be in those same hot spots, even though they might have been generated originally by the same nuclear event.

In other words, they would be more long-lived and would be more likely to circulate all over the world over a period of time and be a hazard for a longer period of time than would Iodine–131?

Dr. HOFFMAN. That is true. However, you also have to question whether or not you could see Strontium–90, Cesium–137 that originated from Nevada in these locations. And, the answer is that yes, indeed, those radionuclides are present at those locations. However, their presence may be masked by a larger fraction that was deposited with global fallout.

Senator GLENN. OK. But does strontium concentrate in the bones?

Dr. HOFFMAN. Yes.

Senator GLENN. Has anyone ever done studies in these same hot spots to determine whether we have higher incidence of bone cancer that might be trackable back to strontium?

Dr. HOFFMAN. I do not believe so, and I believe that such studies would be difficult because of the other potential causes of bone cancer. So, that a simple epidemiological study that tries to do a geographical analysis of bone cancer and to draw correlations more likely than not might produce inconclusive results.

Senator GLENN. OK. I have nothing else.

Senator COLLINS. Thank you very much for your testimony.

Our next panel this morning includes the official who managed the radiation study, Dr. Bruce Wachholz, the Chief of the Radiation Effects Branch of the National Cancer Institute.

The Department of Health and Human Services is represented by Dr. William Raub, the Deputy Assistant Secretary for Science Policy and the Science Advisor to the Secretary of HHS. HHS is the Department ultimately responsible for the oversight and management of the NCI study.

I am also going to ask that Dr. Richard Klausner, the Director of the National Cancer Institute, join these other two witnesses. I would ask that the three of you come forward and remain standing so that I can swear you in pursuant to the Subcommittee rules.

Do you swear that the testimony you are about to give will be the truth, the whole truth and nothing but the truth, so, help you, God?

Dr. WACHHOLZ. I do.

Dr. RAUB. I do.

Dr. KLAUSNER. I do.

Senator COLLINS. Thank you. Please, be seated.

I first want to just go over the ground rules for the testimony. Any written statements will be submitted in their entirety. I am going to ask that oral statements be limited to no more than 10 minutes each, using the lights for guidance. I want to start with

Dr. Wachholz. Do you have a statement that you would like to make this morning?

TESTIMONY OF BRUCE WACHHOLZ, PH.D., CHIEF, RADIATION EFFECTS BRANCH, NATIONAL CANCER INSTITUTE

Dr. WACHHOLZ. Yes, Ma'am.

Madam Chairman, Members of the Committee, I am Bruce Wachholz, Chief of the Radiation Effects Branch at the National Cancer Institute. In that capacity, I have had the opportunity to oversee a wide range of radiation research projects funded by the NCI and have worked with scientists in other Federal and non-Federal agencies and laboratories for 15 years. Also, here today from NCI, to my right, are the Director of the Institute, Dr. Richard Klausner, and behind me, the U.S. Associate Project Director for the Chernobyl Studies, Dr. Ihor Masnyk.

I would like to ask that the NCI statement be included for the record, as I am sure Dr. Klausner would request.

Senator COLLINS. It will be.

Dr. WACHHOLZ. First of all, I would like to express my personal appreciation to the Subcommittee for its clarification of items in the press that occurred yesterday. It is very much appreciated.

One of the NCI projects, the preparation of the I–131 Fallout Report, unfortunately took 14 years to complete. Too many years. That was for two reasons. First, the recruitment of all the experts involved in the study, the data collection, management and analysis, computer programs and drafting of the report took roughly between 10 and 11 years—much longer than either the advisory committee or I originally predicted, but not inconsistent with other studies of this type.

Second, and perhaps more importantly, for almost 2 years, from 1994 to 1996, the preparation of the report received little attention. I sincerely regret that this has happened and I take responsibility for the delay and acknowledge that the report could have gotten out faster.

One of the concerns expressed by the Subcommittee has been that those of us involved in the report—and I certainly include myself in that group—should have been more sensitive to the public's interest in the findings, and we should have involved the public more in its development and dissemination. In retrospect we should have involved citizens in some way in all aspects of the project.

We did provide continuous presentations to the scientific community at meetings of National Cancer Institute Advisory Boards, groups at international and national meetings and to other Federal agencies who assisted with the methodology. As the previous participant, Dr. Hoffman, mentioned, it was discussed in the scientific community.

There was no intent to deceive or to conceal this information from anyone, including the public. It, perhaps erroneously, never occurred to me that the delay in publishing would be interpreted as a so-called coverup or concealment of data.

In fact, one of my primary efforts in the preparation of the final document was to ensure that the various categories of persons, various diets and so on, be clarified in the report so that those persons in the public who might be interested in the report would be able to understand the information more clearly and have the opportunity to construct their own estimated doses. This required extensive rewriting of the document to make it as user-friendly as it now appears in print and on the Internet.

The recent review of the report by the National Academy of Sciences found it to be a careful, detailed and responsible effort with scientific results consistent in most respects with the Academy's own analysis. But the reviewers also recommended that a focused effort be made with the help of the public to develop a program of public information and education about the consequences of the Nevada weapons tests.

I am aware of the criticisms and concerns expressed by many about the length of time it took to make our findings available to the general public. And I agree and subscribe certainly to Dr. Klausner's statement in last October's hearing on this same matter, that a clear, faster and more aggressive plan should have been put in place to make the results public.

During that same time period, from 1991 forward, non-government scientists, NCI staff and I were involved in developing long-term studies of health effects, specifically of the thyroid that might result from exposure to I–131 from the Chernobyl Nuclear Power Plant accident in 1986. We hope that these studies will provide a more definitive answer in order to assess the risks of thyroid cancer associated with exposure to I–131 and, thereby, help to respond to the third component of the Congressional mandate.[1]

However, this is a long-term clinical epidemiology study in countries of the former Soviet Union where we face many challenges. I surely have learned from the I–131 Report experience that this research is of interest not just to scientists but also to the medical profession and to the public. Therefore, we are all making efforts to inform the public as new information becomes available.

For example, last December we presented the I–131 Report to the Centers for Disease Control and Prevention Advisory Committee on Energy Related Epidemiologic Research, referred to as ACERER, which includes both non-government scientists, such as Dr. Hoffman whom you heard from earlier, but also members of the public. And we are scheduled to discuss the Chernobyl project with the same advisory committee in November of this year.

In addition, last week our contractor at Columbia University, who is working with us on the Chernobyl studies, and I presented these studies to the National Cancer Advisory Board—which also includes members of the public and medical professionals. The CDC participated in that presentation, as well.

These Chernobyl studies are the result of interagency cooperation and could not have come about without the help of the Nuclear Regulatory Commission, the Department of Energy, NCI staff, and many non-government scientists with special expertise who are willing to devote their time and effort to overcoming the challenges involved in helping Belarus and Ukraine conduct these studies.

We have resolved the many and challenging difficulties that have come to our attention so far and I am glad to report that screening of populations is underway in both Ukraine and Belarus. In fact, in the first year of screenings, Belarus is very close to meeting its projected target for participant accrual.

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[1] See Exhibit 13, which appears in the Appendix on page 893.

When asked last week at the National Cancer Advisory Board's open session about the progress of the Chernobyl project, Dr. Jeffery Howe, who leads the contract with Columbia University to provide scientific and technical support in aspects of these projects, said it quite well and I quote, ". . . all epidemiology takes a long time to get going. So, despite the apparent length of time I was not surprised and was not discouraged. And . . . since I have been actively involved in the thyroid studies, I have actually been very impressed that things are moving now. . . ."

We, at NCI, share his optimism and are encouraged by the pace of accrual. Shortly, Bi-National Advisory committees will meet to discuss how they can best advise all entities involved about the progress of the project and how to maintain the integrity of the research. Our foreign colleagues and we look forward to receiving their guidance, including how best to communicate information as it becomes available.

We know that communicating results of our radiation studies to the public requires a careful and thoughtful plan and my colleagues and I will be mindful of that in the future. In fact, we will work closely with the CDC in order to plan for future information for the public in a more thoughtful and sensitive manner.

That concludes my remarks. I would be happy to answer questions.

Senator COLLINS. Thank you.

Dr. Klausner, I know you have submitted a written statement for the record. Would you like to make a few brief remarks?

Dr. KLAUSNER. Yes.

TESTIMONY OF RICHARD D. KLAUSNER, M.D.,[1] DIRECTOR, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. KLAUSNER. Let me just respond to a few issues that have been brought up about how we communicate this very important and troubling information to the public. Once I became aware of the study, which was in the spring of 1997, we moved very, very quickly to make sure that this is presented to professional communities, public health communities, and to the public.

This report was unprecedented, in that it was 110,000 pages. It was very complex and we wanted to make it in a form—and it is very hard to do, and there is lots that we can do better—accessible to everyone.

We put it out on the Internet. Individuals can go in and can reconstruct their own predicted doses, based upon where they were born, when they were born, and if they can remember, what they ate and how much they drank—recognizing that there are great uncertainties here.

We met with and spoke with all State and territorial health officials. We had an extensive communication plan with professional societies, including the American Thyroid Association. There were special sessions at those meetings to develop what they would say to their members so that we would put out the information that you and Senator Glenn have asked for: What should physicians say? What should individuals ask? Where they can get information?

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[1] The prepared statement of Dr. Klausner appears in the Appendix on page 75.

We had many press conferences. The press certainly was very helpful in making sure this is a very widely known report. We were moving to release it as quickly as we could in, as I said, an unprecedented way.

We have a lot of communication mechanisms at the NCI. The most widely used service for getting free information about cancer in English and in Spanish is available through a 1–800–number [1–800–4–CANCER], and we had questions and answers put there.

We did an enormous amount last year—and continue to help work with professional societies to get this information out and to put it in the context of what to do, what we know, and how much about this we do not know. There is still great uncertainty about the implications.

Importantly and largely because of the question of whether the Federal Government is credible about these issues—because of this terrible history and legacy of secrecy and what the government had done—we turned to an independent entity, the Institute of Medicine and the National Academy of Sciences, so that they could look at the study, if it was well done, if it was credible and, specifically, to make advice to all of us—to the Nation—about what we should do in terms of public health implications, medical monitoring implications, and advice about what we should do for education and communication.

I know that we can do everything better but I want to assure you that ever since this report came to my attention I think we have moved in an unprecedented way to be open, to be communicative, to provide the type of information that you have been asking for today, and the type of information that Dr. Hoffman has talked about.

One final thing. The CDC has done a spectacular job with radiation-related studies, including the Community and Oversight Boards. What we have done since a year ago is sign a memorandum of understanding between myself and the head of this area of the CDC. All NCI radiation studies are now presented to the CDC's Public Oversight Board to correct what we saw were deficiencies in the process and which I know you are concerned about.

So, I just want to assure you that we have been acting.

Senator COLLINS. Thank you.

Dr. Raub.

TESTIMONY OF WILLIAM F. RAUB, PH.D.,[1] DEPUTY ASSISTANT SECRETARY FOR SCIENCE POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. RAUB. Thank you. Madam Chairman, Senator Glenn, I am pleased to present the perspective of the Department of Health and Human Services on the conduct of two studies designed to examine the effects of exposure to Iodine–131 following nuclear testing or accidents.

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[1] The prepared statement of Dr. Raub appears in the Appendix on page 87.

My colleagues and I appreciate the time and attention the Subcommittee staff has devoted to its review of these studies. The Department recognizes as understandable and legitimate the frequently expressed concern that the exposed populations in both cases may be at higher risk of diseases of the thyroid, particularly cancer.

We share your desire that our research be conducted both rigorously and efficiently and that outcomes be used to promote national policies that are protective of the public health. The National Cancer Institute is the appropriate organization to direct research toward resolving these concerns. It has the requisite expertise and experience. In particular, its staff includes leading international authorities on radiation epidemiology and radiation dosimetry.

The Subcommittee has raised important questions about our response to Public Law 97–414, which directed the Department to conduct the study related to the Iodine–131 fallout from the Nevada Test Site. NCI clearly took too long to complete the study. We have learned important lessons about use of resources and the setting of priorities as a result of our experience with the Iodine–131 study. NCI already has instituted important management reforms to ensure that repetitions of this do not happen.

The Department, for its part on a broader basis, will review its procedures for monitoring such major studies and, where necessary, will institute reforms to ensure that we do not repeat the experience of the Iodine–131 study.

As you know, the Institute of Medicine reviewed the NCI study and recently issued its own report. IOM assessed the soundness of National Cancer Institute's analysis and assumptions and its estimates of risk of thyroid disease from Iodine–131 fallout. IOM also analyzed the issues associated with population-based screening for thyroid cancer and the challenges associated with providing clear and useful information about the risks of both radiation and screening to those who have been exposed. We are currently studying IOM's report so that the Department can be responsive to its findings.

I call your attention to the fact that IOM did not recommend population-based screening for people exposed to radiation fallout. Testimony earlier today from the Agency for Toxic Substances and Disease Registry, however, indicates that it recommends medical monitoring for people exposed to radiation from the Hanford Nuclear Reactor. In his testimony, Dr. Johnson, of ATSDR, compared his agency's recommendation with the IOM findings. He correctly noted that ATSDR, and NCI studies differed considerably with regard to circumstances, methodology, outcomes, and requirements. On their face, the ATSDR and IOM conclusions do not appear to be in conflict.

However, the Department will review policies and practices at the Centers for Disease Control and Prevention, ATSDR and NCI to identify significant differences, if any, in their respective approaches to dose reconstruction and determinations regarding the need for and feasibility of population-based screening or medical monitoring.

If we find any differences that we believe jeopardize the Department's ability to be protective of the public health, we will initiate corrective action.

The ongoing NCI study of the Chernobyl disaster is a unique opportunity to examine the effects of radiation on people. We have confidence that the Institute is on course toward identifying proper cohorts, estimating exposure, and assessing risks of disease.

The Department is aware of the difficulties of conducting such research in countries that had been part of the former Soviet Union. The science of epidemiology is not as uniformly well developed there as here. In many cases resources and experience lag far behind those available in the United States, and managing a major international study in an area of the world that is experiencing significant political and economic instability is a difficult undertaking.

As a consequence, I do not think we should judge the progress of the Chernobyl study using the same standards that we would apply to a study conducted in the United States. Nevertheless, the Subcommittee staff, in its discussions with us preceding this hearing, raised several important management issues related to the Chernobyl research.

Because this research is so important and, we hope, the only opportunity we ever have to study such exposure in human beings, the Department wants to be certain that the Chernobyl work is done as effectively and as efficiently as possible. We recognize the concerns of the Subcommittee, and we take them seriously.

I will work with NCI staff to arrange for an independent review of the Chernobyl project to identify any problems associated with the way the work is planned, organized, conducted, and overseen.

Our plan to seek an independent review does not mean we lack confidence in the National Cancer Institute. To the contrary, we believe NCI is the right organization to conduct this research, and we are intent upon doing everything reasonable toward ensuring that the project remains appropriately oriented and proceeds as expeditiously as circumstances allow. We will await the outcome of the independent review with an open mind.

Thank you for the opportunity to testify today.

Senator COLLINS. Thank you, Dr. Raub.

Dr. Wachholz, I want to get in my mind a clear understanding of the timetable and also the reasons for delay. Dr. Hoffman testified this morning that the NCI report was essentially completed in 1992, is that correct?

Dr. WACHHOLZ. The data base and most of the analysis were complete by that time, yes, Ma'am. The report, itself, in its entirety was not complete until 1994.

Senator COLLINS. All right. I will accept the 1994 date then for the purposes of this discussion. Considering that the study's findings were that people in unexpected areas of the country, including States like Maine, were exposed to high levels of radiation, why did you wait so long before releasing this information to the public?

That is the question that I am having a great deal of difficulty with.

Dr. WACHHOLZ. Understandably so, Madam Chair.

I have to take you back to that time. Quite candidly, there had been literally no inquiry with regard to this particular study during the preceding 10 or 11 years. In addition, our Advisory Committee had been disbanded in 1993. Certainly wrongly in retrospect, obviously, the sense was that nobody was really terribly interested in this. That, in and of itself, is not sufficient.

I think you also have to keep in mind that concurrent with those times we were becoming increasingly involved in the Chernobyl studies which were taking a great deal of time, particularly from 1993, 1994, 1995, and onward. We could not do both with equal dedication.

Given the situation at NCI at that time, when there were uncertainties and changes in management in 1993, 1994, and 1995, I had to make a decision as to whether or not we would make a major effort to establish ourselves in the countries of the former Soviet Union in order to work with the governments there in order to address the third component of the law that has been mentioned earlier, namely the risk co-efficient for thyroid cancer—versus getting the report out and letting the Chernobyl study pass essentially—and we could not do both with equal dedication at that time.

Senator COLLINS. The public cannot be interested in what the public does not know. The interest in this report was enormous once it finally was released. Was there any concern on your part that, did you delay for any reason, related to your concern about what public reaction to the report might be?

Dr. WACHHOLZ. No, Ma'am.

Senator COLLINS. Was the report only released when Congress started pressuring the agency, saying, where is this report? We were notified back in 1992 by the NCI that we were going to receive it in 1992.

Dr. WACHHOLZ. When Dr. Klausner and his senior staff became established in mid-to-late 1995, the situation was discussed with my supervisor at that time, and steps were taken to augment the staff. So, starting in 1996, I could devote time to getting this report out.

In early 1997, I think, I wrote a letter to CDC responding to their request as to when the report would be out. I think I indicated at that time that we were hoping to have it out by October 1, 1997, which predated any of the press involvement. We recognized ourselves that we just had to get this report out and once we had a management structure in place to be of assistance in this, we made progress on it.

Senator COLLINS. I know that Senator Glenn is going to want to follow-up on those issues. I am just going to ask one question of Dr. Raub before turning over the questioning to Senator Glenn.

Does not HHS bear some responsibility here? It was HHS' decision to delegate the report to the National Cancer Institute. How did HHS let such an important study fall through the cracks? Do you not have a system for tracking congressionally mandated studies?

Dr. RAUB. Madam Chairman, you are right. The Department does bear responsibility with NCI here. The system for tracking congressionally mandated projects clearly failed in this instance.

Senator COLLINS. Senator Glenn.

Senator GLENN. Well, is there a system?

Dr. RAUB. Yes, sir. It is not clearly as uniform as it ought to be but there are attempts, especially with appropriations actions within the Department, to try to ensure that there is systematic follow-up. We clearly have not done as good a job with respect to mandates occurring in legislation outside of appropriations.

Senator GLENN. I would think this would be fairly simple, not only in your office, but out in NCI also, Dr. Klausner. You came in 1995, so, a lot of this pre-dates your arrival there. But any big endeavor like the Department's or agencies that you operate will often have a big board on the wall or a pert chart where you list the different things and when they are due. The list includes all these things, including due dates and whether it either made it or it does not.

How do you keep faith with the people who asked for this report? There apparently is no such system operable. Or, at least for this report, if there is, it really fell through the cracks because we are talking about 14 years.

And we are talking about even when we received annual reports from NIH and the annual reports of the National Cancer Institute from 1992 to 1995 regarding this report, the report stated that the activities, "Have been completed during the current reporting period."

Each year they are telling us over and over again the report has been completed and then additionally the Advisory Committee for the study was even disbanded in 1993 as you have mentioned, Dr. Wachholz. So, here we have a study all completed and nobody is checking on it to see that it just gets submitted.

Now, somewhere, obviously, things fell through the cracks and Dr. Wachholz is taking complete responsibility for this. I gather that you had competing things demanding your time. Are you short-handed? Do we need more support in these areas? Obviously the squeaky wheel gets the grease at NIH or NCI or any place else and if we are not griping about not getting a report, maybe it gets shifted back some place and that is not the way the system is supposed to work.

We should not have to heckle people into getting a report once the thing is done. It should not sit out there for years. And you have already admitted that this report fell through the cracks, but this makes me wonder how many more reports have been requested for very good reasons, people doing studies and so on and concerns about health, and how many more are sitting some place because there is not a system in place to make sure that we get them moving off dead center and in here somewhere close to their deadline.

Now, do we have a system or do we not? I will start with you, you are HHS, and then I will go to Dr. Klausner and see what kind of a system you actually have right now.

Dr. RAUB. The system that exists now, Senator Glenn, is oriented heavily toward those requirements that are associated with appropriations bills, as I indicated. I am not aware that we are remiss in failing to track or report other mandated studies, but I could not at this moment give you assurance that we are not.

Senator GLENN. What you are saying is, unless it is an appropriations bill then it is going to get sent back to second status, is that correct?

Dr. RAUB. No, sir. I did not mean to imply that, but rather that I believe the system is better developed with respect to appropriations language.

Senator GLENN. Well, we are not an appropriating committee over here and, yet, we ask for studies. This Committee, as a matter of fact, I think we have a record on this Committee. We did not set out to do it that way. But we have the broadest areas of responsibility on this Committee of any committee in the Congress. We overlap almost every other committee. Most people do not realize that. And we normally have the most General Accounting Office studies, for instance, going on behalf of this Committee.

And, so, we probably have a lot of requests out there and I do not want to think because it does not involve an appropriation matter that we are going to get second-class treatment, unless we are notified. If somebody says we have got an appropriation matter and they are demanding action right now, we got to get that thing out there for them, right now, I understand that. The appropriations are the big stick around here and that is understandable. But then if it comes at a time when we have said we would like to have it by a certain time and you have agreed it is going to be by a certain time, then we should be notified of that. And we are very understanding of the appropriations problems.

But we cannot have anything like this dropping through the cracks where it sits for 14 years although it was done in 1992. And in 1993 you disband the committee and we are still sitting. And it does not see the light of day until Senator Daschle's staff, I believe, made an inquiry in 1997. That is how it finally came to light that it was not up here.

Maybe some of the rest of us should have our own little checkoff lists up here, too. But I would hope that we do not have to go through that. We should depend on you to do that for us.

Dr. RAUB. You are absolutely right, Senator. We should ensure that the system is uniformly effective.

Senator GLENN. Good. What do you have, do you have a big chart in your office out there, Dr. Klausner? And if not, why not?

Dr. KLAUSNER. No, I do not. But what we——

Senator GLENN. Well, you are going to develop one real quick, are you not?

Dr. KLAUSNER. No. Actually we have already done it and it is on the computer screen. But there was no uniform tracking system and this issue brought that to light. So, what we have developed over the last year is what we think is a very good computer-based tracking system for all Congressional requests, all reports, wherever they come from. It will be automatically updated so it will automatically generate the progress reports.

We did not have that system before. It will be fully operational this Fall. We have been prototyping it and developing it over this past year. And I think that is exactly how this happened.

When I came in to head the agency there were thousands of projects and I simply did not learn about this project until it was brought to my attention. And you are right, it was from a letter from Senator Daschle that I realized that this was something that had been requested by the Congress.

Senator GLENN. OK. Everybody is saying we did wrong on this and we are going to correct it and all that. Let us move on to Chernobyl. I am concerned about that, because as I understand it, that is supposed to provide us and other countries around the world with a great deal of information about the relationship between radioactive iodine and thyroid cancer.

Although it is not our country, they gave us permission and we are quite happy to come in and do this study working with their people. And normally in doing these things we have a protocol set up on how it is going to go. And that is what we call these arrangements made, governed by scientific plans, it is a scientific plan called a protocol. And these protocols were signed in 1994 by a number of countries. And there was supposed to be a committee to oversee that, an advisory committee, as I understand it. And they would manage and oversee our involvement in that study.

Now, that was to be several different countries represented. What is the status of that? As I understand it, when did those people get appointed? This whole thing started way back. Dr. Wachholz, you were asked in 1994 to appoint five individuals to that committee. When were those people nominated or selected?

Dr. WACHHOLZ. We began identifying people and inviting their participation in 1996. And the delay there, if you read the protocol—with your permission I can read the relevant section or sentence.

Senator GLENN. Certainly.

Dr. WACHHOLZ. "With the approval of the project by authorities of both countries and assurance of funding by both sides, the oversight group or advisory committee would be confirmed."

The assurance of funding really did not occur until 1996, both in their governments as well as financial support from the United States to the scientists working on these projects in Belarus and Ukraine.

Senator GLENN. You did not name the board then for that length of time because the funding was not there to establish the board or what?

Dr. WACHHOLZ. That is part of it. The other part is that the studies actually began in terms of involvement of subjects of the study in 1997 in a serious way.

Senator GLENN. Well, we had the original plan that called for conducting this study in Belarus and it is about 4 years old now. Can you tell us how many people were supposed to have been screened by the end of 1997, by the end of last year and what our status is in that?

Dr. WACHHOLZ. Senator, I will be glad to answer your question but could I put it in context first?

Senator GLENN. Sure.

Dr. Wachholtz. We are dealing with systems over there that do not have a history of research in the context that we are talking about here. Between, for example, 1994 and 1996, there were three changes in ministers of health in Belarus, there were six changes of ministers of health in Ukraine. In Belarus, also, we faced changes in the directors of the institute that we are working with, as well as many of the senior staff. This led to a great deal of difficulty.

Also, we learned, for example, that the signature on the agreement in 1994—by the minister of health of Belarus—had not been validated by the Council of Ministers of the President of that country. That did not occur until 1996.

So, I am just giving you the very tip of the iceberg of the type of problems we have had to overcome there. These are their people, their scientists. We are working with them, but we are not conducting the study. And we have to adjust our expectations to the realities that we find over there that are different every time we go over, literally.

Senator GLENN. OK. Now, you have been operating pretty much without this advisory committee then that was not possible to set up, you say, until some time in 1996. Then you have been operating just sort of out of National Cancer Institute, yourself?

Dr. WACHHOLZ. No, sir.

Senator GLENN. Or how?

Dr. WACHHOLZ. In the early 1990's, when NCI first began to get involved in this at the request of the Department of Energy, we established a working group under and associated with the Fallout Advisory Committee that was subsequently disbanded in 1993.

There were 10 people on this working group. Roughly half were Federal scientists and half non-Federal scientists. Most of those people are still working with us today. That group was called, for shorthand, a working group, which dealt with both countries. That existed until September 1996.

From 1996 on, the individuals were still working with us, not as a group, but as consultants, essentially. So, all the way along this entire development we have had people outside the government as well as inside the government working with us, giving us guidance on all aspects of things—including people in other agencies, and the State Department, and the embassies—on how to face the problems we have come up against.

In 1996, Dr. Klausner met with senior officials of the Department of Energy and decided that because these studies were imminent in terms of their implementation, we would need to augment the resources available within this country. The decision was made at that time to go out for a contract for scientific and technical involvement on a more broad-scale basis because many of the people that had been working with us, if I may say so, are very senior citizens. I hesitate to say that to you, sir, but——

Senator GLENN. That is quite all right.

In some of my endeavors, age has become an advantage not a disadvantage. [Laughter.]

Dr. WACHHOLZ. The contract was let at the end of September 1997. Since then we have had access to additional outside expertise through the contract, as well as from the people that have been working with us all the way along the line.

So, through this entire period it is not just NCI or our organization that has directed or controlled this study. It has involved a lot more people than that.

Senator GLENN. Well, I understand that. My big concern is that we are about 12 years after Chernobyl and every year, every month that goes by it gets tougher and tougher and tougher to contact the people and do the studies and find out who is where and all the rest. So, we have got everybody dispersed and as you say, there have been many changes of administration. There may be more one of these days, we do not know.

But anyway we are going through a time period where time is of the essence and we are letting it get away from us. Now, maybe it has not been under your control, but we had planned by this time, by some of the figures I was given, the original plan called for us by the end of 1997 to have screened some 15,000 people. What we were able to do, we have had 3,500 contacts and we have had 2,900 who have been screened.

Now, maybe that is a sample large enough to tell us a lot. I do not know. Maybe we can get as much out of 2,900 as we would if we had done the whole 15,000. That was in Belarus.

In the Ukraine, the original plan was to have screened 30,000 people and today we have had 800 contacts and 530 screened. And maybe there have been all the management and the funding problems but I am concerned that this is beginning to get away from us as far as time goes.

Is there a management plan, a management structure in place that is really managing this and are the pieces beginning to fit in there and we are ready to go? Because pretty soon you begin to raise the question of whether money spent on this is going to be worthwhile.

After we get up to 15 years or so, if we have not found out something about what happened at Chernobyl or do not have enough cooperation from them or funding or whatever, why I think we need to begin to think about the viability of it and whether it is worth the candle here.

So, I would appreciate your comments on that. Do we now have a management structure in place? And then, Dr. Klausner, I would like to have you comment on it also. Something has to be managed here to the point where we either get results one of these days, after 12 years, or let us just say it was a bad deal and we will forget it.

Dr. WACHHOLZ. Senator, I know it has been 12 years since Chernobyl. The involvement of our activities obviously has been less than that. But in terms of the delays, and you mentioned Ukraine specifically, the Ukrainian Government imposed the regulatory constraints on us at the end of 1996 that precluded us from doing anything until earlier this year.

I think now that we have resolved those they are beginning to get started. As you indicated, with 529 participants. That is just their effort since, I think, May or June. We anticipate that that is going to pick up rather dramatically over the next several months or year.

In Belarus, once the screening was to be started, I think that the first year of screening the protocol originally had projected 3,000. We are pretty close to that. Whether we can keep that up or not will depend on circumstances over there. Certainly we have to adjust as we go over there every time.

In terms of the long-range plan, the protocol is the ultimate long-range plan. But in terms of developing the resources and the financial support to do this, we are working on that, so that we do not run into the same problem that we ran into on the fallout study.

Senator GLENN. Dr. Klausner.

Dr. KLAUSNER. Senator, I think that all of us who look at this study recognize how important it could be and how difficult it is going to be. We should be under no illusions. For many of our clinical studies where there is a clinical epidemiologic study, there are tremendous difficulties and over there the difficulties are amplified.

I wish I can guarantee the rate at which we would get a result. We certainly want to make sure these studies are completed. One of the reasons that we had this presented to our National Cancer Advisory Board is to ask those questions.

The delay from beginning was getting an infrastructure in place. I think the original protocol was very unrealistic and it was written as if it was doing a study in the United States and as if there was an infrastructure to do this sort of study. It has taken the last several years to build the infrastructure, to build relations, to build trust, to build expertise, to build data bases, to translate things.

I think the most important thing—from my oversight of it, to see how it is going, and for the National Cancer Advisory Board—is that once we got to that point of getting an infrastructure in place so the study could happen: Is the rate of identification of the cohorts, the rate of response of the individuals, and the rate of screening, going up? Is it increasing? Does it look like we are going to achieve the milestones? So far it is looking optimistic.

I do not want to overstate that. This is going to be a difficult study to complete. But it is progressing and I think the entire Advisory Board really felt that. They mostly felt how amazingly difficult the challenge of the study is going to be but that once we have gotten the infrastructure in place and they actually began screening, the rate of screening is not very far from the projection in terms of the quarterly rate.

Senator GLENN. Well, correct me if I am wrong, but my understanding is that some of the other nations have been in there looking at these things, too, and doing screening and I do not know what their problems are. But I understand, I have been told anyway that the Japanese have already screened 160,000 kids between 1991 and 1996.

Why can they do these things and we cannot? What is the problem?

Dr. KLAUSNER. The nature of the studies is really quite different. There have been thousands of publications already that have come out from studies related to the Chernobyl accident. But to attempt to do the type of study that has never been done—a careful dosimetry, dose reconstruction—so that we ultimately can actually have not estimates but a real assessment of what the risk is in humans, as a function of age and gender, from a dose of Iodine–131 received? What is that risk of getting cancer over years? That has not been done.

I think the complexity of this study, the importance of this study, is just that. But with that importance is an increased complexity that is different from a lot of the other studies, for any of the other studies that have been done.

Senator GLENN. Well, they went in there, their study had a different purpose than ours, is that correct?

Dr. KLAUSNER. Yes, I believe that is right.

Senator GLENN. Correct, Dr. Wachholz?

Dr. WACHHOLZ. Yes, sir.

Senator GLENN. Yes. The 1994 protocol called for an annual report to the Advisory Committee. That report is supposed to assess organization of the study, progress, staffing, equipment, status of locating subjects, fiscal report. Has such a report ever been prepared?

Dr. WACHHOLZ. No, sir, there is no report of the Advisory Committee because there is no Advisory Committee at this point. There are progress reports from the countries on a quarterly basis, but they have not been consolidated into an annual report.

If I may, sir, you are focusing on the Advisory Committee. We, at this point, do have an Advisory Committee, and we have had one on several occasions in the past. But for one reason or another people have had to withdraw because of either actual or perceived conflict of interest.

As of this date we have identified individuals for the U.S. component. We have their counterparts from Belarus and Ukraine and we certainly expect to schedule a meeting as soon as we can get everyone's calendar to match.

Senator GLENN. I am concerned about the management structure and Dr. Klausner, maybe you ought to comment more on this. I would ask, first, do we at this time have a project plan on this? Do we have a 3- and a 5-year budget plan for equipment and supplies and people and——

Dr. KLAUSNER. Yes.

Senator GLENN. Where are we going with this thing? Is it now, in other words, organized or do we need to ask you to have a report from you within 30 days where you detail what the plan is and the management structure or——

Dr. KLAUSNER. I would be delighted to provide one.

Senator GLENN [continuing]. Or can you assure us today that it is all set up and ready to go?

Dr. KLAUSNER. I can assure you today that it is going. It is happening. I think, again, part of what is difficult about this is that given the nature of the study we have to be nimble and flexible. We keep running into problems. We discover them. We run into the need for new expertise. And we need to be able to respond to that.

We can get into sort of "the best laid plans of mice and men." We can have a written out protocol. We are trying to follow it. I can and will be happy to provide for you a description of how we are getting the studies done. There is a management structure. There is a reporting structure. There is a project director. I want to emphasize the project director in Belarus is a Byelorussian scientist and the project director for the Ukrainian study is Ukrainian. We are advisory to them and we work with them.

The major way that we determine the budget is that we have a 3-year contract, with Columbia University; so we have a 3-year budget, with a 2-year period of award increase. That is the way we budget these sorts of projects. That is the way we always budget them. We have interactions with the NRC (Nuclear Regulatory

Commission) to provide for equipment and, in addition, we have the updated estimates that I get with each annual budget from the division that Dr. Wachholz is in, what we are going to need to support new meetings, travel and that is approved every year.

We are committed to this. We only have, as you know, 1-year funding. But we plan for multi-year projects. That is what we do for all of our projects. I am happy to provide that for you in writing.

Senator GLENN. Well, staff was informed that there are no 3- or 5-year budget plans for equipment and supplies, is that correct?

Dr. KLAUSNER. I have been given a projection of the estimate of the next 3 years' budget. These are changing year-by-year as we see, for example, whether a van breaks down and then we need to buy a van. I think that is the nature of this. We are committed to try to find the dollars. We have a base budget which we think are the predicted costs that we are going to need to fulfill the contract, to fulfill the staff obligations, and a commitment for equipment.

What happens as you go along all of these long-term projects is that there are, in fact, unexpected costs.

Senator GLENN. I understand that but do you have the overall plan, a 3- and 5-year plan for equipment and supplies? Is that in place now, so, we know what is going to be expected?

Dr. KLAUSNER. I can give you the 3-year—which is all that has been presented to me—estimate of what dollars are going to be needed in each fiscal year for this project. I have that, as we do for all of our clinical trials. But I will emphasize that they change, essentially, yearly.

Senator GLENN. I understand the change, but what I am concerned with is there is a management structure that even if it changes year-in/year-out, we have a structure here that is dealing with this on a year-in and year-out basis.

Dr. KLAUSNER. Yes, we do.

Senator GLENN. And if you have it for the 3-year plan, could we have that submitted to the Committee for our records?

Dr. KLAUSNER. Sure.[1]

Senator GLENN. Then we will know what your planning is in that direction.

Dr. KLAUSNER. Sure.

Senator GLENN. And do you have milestones and hurdles you expect to hit, Dr. Wachholz? Do you have things in here that you hope to accomplish by a certain time and have some idea now that after all this time we are going to get the information we need?

Dr. KLAUSNER. Well, as you pointed out, our original projections for time factors and when things would be accomplished was rather unrealistic when we came face-to-face with reality over there.

We have learned from that and, so, our milestone projections at this point are basically on a quarterly basis. When we go over there, we work with people, we identify, review and so on, what the previous milestones have accomplished, where they stand and what can be done in the next quarter.

Senator GLENN. Dr. Raub, there seems to be some discrepancy or a great discrepancy in the way that different agencies approach their radiation research, especially with respect to openness and public participation. Obviously we get greater credibility and public acceptance the more open these studies are.

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[1] See Exhibit 6, which appears in the Appendix on page 767.

What are you doing in the Department, what kind of effort are you putting forward to establish a departmentwide policies and guidelines so that there will be a consistent approach to these studies?

Dr. RAUB. Senator, heretofore, we have not. We viewed it as a matter delegated to the respective agencies. As Dr. Johnson indicated before, much of the work at the Agency for Toxic Substances and Disease Registry and the Centers for Disease Control tends to be, to use his phrase, site-specific and, therefore readily focuses on the potentially affected populations. And I believe it has worked well in terms of broader public involvement in those processes.

In hindsight, as indicated also by earlier testimony, the larger NCI study did not do that. In my testimony I indicated that collectively, as the Department, we would look at our practices and procedures related to dose reconstruction and other considerations to ensure that we do not have significant unexplainable differences in our approaches and try to promote, as it is appropriate, a greater degree of uniformity across the Department.

Senator GLENN. OK. I want to commend you and HHS for agreeing, as you said earlier, agreeing to undertake an audit of the Chernobyl, and I look forward to having information from you at that time.

I would say that if you get information that you think is appropriate for the Subcommittee, we would appreciate it being forwarded to the Subcommittee by letter, rather than waiting for a hearing or something.

Dr. RAUB. Yes, sir.

Senator GLENN. Because we will be out of session, this being an election year, we will not be in until January. I would hope we would be getting some information on these very shortly. These are things we have waited for, for a long time.

Now, Dr. Klausner, you said you have thousands of projects out at NCI, which you do. Have you screened those to see if you are overdue by X number of years, months, or whatever, on reports that we have been expecting here or somebody has been expecting for a long time?

Dr. KLAUSNER. I have certainly asked for that. We have been reviewing everything and we have not found anything that at all looked like this 12-year project.

Senator GLENN. Thank you, Madam Chair.

Senator COLLINS. Thank you, gentlemen.

I think that we have learned from this experience. When dealing with an issue that has serious public health consequences, it really is imperative that deadlines be met or that the agencies involved give an explanation to Congress as to why they are not being met.

To fail to do so only creates a climate of distrust, apprehension and fear that is in no one's interests and that can lead to wrong conclusions of conflict of interest or concealment or cover-up being reached.

I do not believe that is what happened in this case. I think it is an example of poor management and of failure to understand the public interest in the report in the sensitivity of the materials. It is, nevertheless, important that these kinds of mistakes not occur in the future and I think that Senator Glenn's emphasis on simply having a system where reports are tracked is a very good one.

I want to yield to Senator Glenn for any concluding comments that he might have or any concluding questions.

Senator GLENN. Thank you, Madam Chairman.

I would just ask that the record be kept open for 10 days so that we might, if other Members do have questions in this regard or if we have some follow-up questions we think about that we should have asked today and did not, we hope the witnesses would respond promptly so that we can get that as part of the record.

So, I would ask unanimous consent that that be the case.

Senator COLLINS. The record will remain open for 10 days for the inclusion of additional materials and possible additional questions and answers for the record as well as any public comments that may be submitted to the Subcommittee.

I want to thank Senator Glenn for bringing this issue before the Subcommittee. It was a very interesting issue. I know that I learned a lot and I believe that we served our constituents well by pursuing this issue.

Senator GLENN. Thank you, Madam Chairman.

I appreciate very much your willingness to hold a hearing on this. I think it is important and I think we have aired this pretty well today. I can see where we maybe have had some deficiencies in the past. I hope, because of this hearing, we will see those things corrected.

Senator COLLINS. Thank you.

The hearing is now adjourned.

[Whereupon, at 12:06 p.m., the Subcommittee was adjourned.]

APPENDIX

STATEMENT OF SENATOR TOM HARKIN

Radioactive Fallout and the NCI Report
Written Testimony

I appreciate the opportunity that the Subcommittee has provided to discuss an issue of importance to the nation, including my home state of Iowa. The lack of medical warning and response to our nation's nuclear weapons testing program in the 1950s and 60s was a huge failure of the government.

Unfortunately, the lack of response continues today. It is, I am afraid to say, an example of the federal government failing to own up to its mistakes and help the citizens it harmed. Despite some efforts by the National Cancer Institute and the Institute of Medicine during the past year or so, I am afraid the federal government's response is woefully inadequate.

I would like to share some of my experience and opinions on the issue that I have garnered over the past year. This is not just a academic subject for me. My constituents are affected. My own family is affected. And I will address that in just a moment.

First, I'd like to discuss why we ended up with so many Americans exposed to radioactive fallout.

Atomic bomb tests in Nevada during the 1950's exposed millions of Americans — particulary children - to large amounts of radioactive Iodine-131, which accumulates in the thyroid gland and has been linked to thyroid cancer. "Hot Spots" — where the Iodine-131 fallout was the greatest — were identified by the NCI report as receiving 5-16 rads of Iodine-131. Outside reviewers have shown that the 5 - 16 rad level is only an *average*, with many people having received much higher exposure levels, especially those that were children at the time.

To put that in perspective, Federal standards for nuclear power plants require that protective action be taken for 15 rads. To further understand the enormity of the potential exposure, consider this - 150 million curies of Iodine-131 were released by the above ground nuclear weapons testing in the United States compared with about three times higher from the Chernobyl nuclear power plant disaster in the former Soviet Union.

Soviet officials eventually evacuated the entire Chernobyl area, after acknowledging the fallout might be hazardous. And, remember, the fallout released in the United States during our period of nuclear testing is nearly 16 times greater than the Chernobyl release. Exposing our citizens to this risk is unacceptable.

The "Hot Spots" included many areas far away from Nevada, including New York, Massachusetts and Iowa. Due to the character of Iodine-131, those exposed to the highest concentrations were those who drank large amounts of milk from cows that grazed in fields with radiation fallout. Because their thyroids are smaller and still growing, children were most vulnerable.

Too often, we have heard from the NCI, "on average, everyone is okay." Well, I'm not talking about the average person. I'm talking about real people who were exposed to radioactive fallout and are suffering as a result.

People like me and my family. During the 1950's, I was living in a rural Iowa county which has now been identified as a "Hot Spot" by the long delayed National Cancer Institute study. Along with many Iowans, I drank milk from cows kept on our farm. This increased the risk faced by myself and my family because of the accumulation of radioactive iodine in milk. There was no delay in our exposure to radioactivity. We were not average people. We were at great risk. As some of you may know, my brother eventually died of Thyroid cancer.

When it comes to the government and nuclear testing, history shows the problem hasn't just been a fallout of radiation, but withholding of facts which may be detrimental to the public health. Information has come to light that government officials were aware that fallout from nuclear testing would contaminate areas that were hundreds, even thousands, of miles away.

Additionally, it is outrageous that the government provided maps and forecasts of potential radioactive contamination to the American corporation during the 1950's and not to the American public. As I've said before, if we could protect a factory, we should have protected the parents and children.

And I am dismayed to tell you that since the NCI report was put out last October, there still has been no concerted effort to release the information. This is a travesty, and we must do everything we can to remedy the problem. The NCI contracted with the Institute of Medicine to review their report before conducting an education campaign. Now overdue, the IOM says that there is no need for screening.

There seems to be an attitude by the federal government that if we give the public too much information, people will overreact.

However, the government has a clear responsibility to its citizens to inform them of the potential risks of exposure and to encourage those at the highest risk to seek appropriate screening and treatment.

The IOM says that no screening of the affected should take place. This is quite a statement considering the number of people exposed and the estimate of tens of thousands of thyroid cancer cases that will result.

I am certainly not a doctor, but I have a problem with NCI's position regarding screening. Their position here needs to examined closely.

It is a reckless endangerment of Americans, and it contradicts common and traditional proactive actions on thyroid cancer risks. Even the American Cancer Society's policies on Thyroid cancer raises serious questions concerning NCI's view on screening.

So what can we do? I see two major legislative initiatives. First, we have inserted in the Senate version of Labor, Health and Human Services Appropriations bill a requirement for additional timely studies on the health effects of radioactive nucleides other than Iodine 131. Second, the ongoing study and health screenings by NCI of Chernobyl survivors needs to have a thorough scientific and management review. This study is of great importance to understanding and addressing the health impact of radiation exposure and Congress must ensure that a quality study is completed in a timely manner.

I must point out that I am not here to crucify the dedicated scientists at the NCI. In fact, they did a great job with the science of nuclear fallout, and I salute them for their efforts in this area.

I do think, though, they did an inadequate job in responding to the human health consequences of fallout exposure. That situation must be rectified quickly, before more years go by, more years with the American public waiting for critical — potentially life-saving — information.

We all have to remember we are dealing with real people, not statistics. Real people who might not have access to regular medical care. Real people who may not always ask their doctors the right questions. There are a lot more issues than I can go into at this time. But I hope this panel will begin to address the need to educate people about the risks they may face.

We must never forget the human face of nuclear testing fallout. There are very real health threats to real people here. Unless we aggressively press for full disclosure and rigorous scientific review of the research, we shirk our responsibility to at-risk Americans. Everyone who is at risk should have the opportunity to make the own, informed decisions regarding their exposure to nuclear fallout.

Congress must weigh more than simply the soundness of the science. We must also remember our moral responsibility. The culpability of the American Government is clear in this case. We exposed American citizens to radioactive fallout and deliberately withheld that information from them. Now it is our responsibility to provide the necessary information and help to all Americans who may be at risk. For the sake of the health of the tens of thousands who were exposed to fallout, we should do nothing less.

Testimony of

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I am here today to testify about the health impact on the American people from atmospheric testing of nuclear weapons at the Nevada Test Site and about the significance of the results presented by the National Cancer Institute in its report on this subject that was published in October of 1997.

PROFESSIONAL BACKGROUND

I am trained as an environmental scientist with more than 25 years' experience in the field of environmental radioactivity. During my career I have studied various aspects of the environmental transport and health consequences of iodine-131 and other radionuclides released from nuclear facilities.

I am now president and director of SENES Oak Ridge, Inc., Center for Risk Analysis. Prior to 1992, I was employed in environmental and health sciences at the Oak Ridge National Laboratory for 17 years. From 1988 to 1996, I also held the position of Chief Scientist for the International Atomic Energy Agency to test the accuracy of computerized models that forecast the environmental transport of radionuclides using data sets obtained from the aftermath of the Chernobyl accident. I am currently a member of the National Council on Radiation Protection and Measurements (NCRP), the Radiation Advisory Committee of the EPA Science Advisory Board (on which I chair the Subcommittee on Uncertainty in Radiogenic Cancer Risk); and a corresponding member to the International Commission on Radiological Protection (ICRP). I am also a member of the Advisory Committee to the Department of Health and Human Services for Energy Related Epidemiological Research (ACERER). I hold memberships in the Health Physics Society, the International Union of Radioecology, the International Society for Exposure Analysis, and the Society for Risk Analysis.

MY ASSOCIATION WITH THE NCI STUDY

In 1987, while I was at Oak Ridge National Laboratory, I performed experimental field research for NCI to estimate the amount of soluble and insoluble radioactive fallout in rain that would be intercepted and retained on various species of pasture vegetation and on gummed film. I also served NCI as a consultant (unfunded) to attend meetings during the late 1980s and very early 1990s to advise on methods for estimating uncertainty in dose calculations.

In May of 1996, as part of the Oak Ridge Dose Reconstruction Study for the Tennessee Department of Health, I performed dose and health risk assessments of I-131 in NTS fallout at Oak Ridge using data obtained from NCI on calculated concentrations in milk. In December 1997, as a member of the ACERER, I attended the first public briefing by NCI on the findings of their study, at which time I offered numerous comments about the study, including the need to include estimates of health risk the need to disclose the high doses that would result from children who consumed goat' s milk, and the need to identify the authors responsible for the report. Later in that month, I became a consultant to the National Academy of Sciences/Institute of Medicine (NAS/IOM) committee charged with review and analysis of the NCI report.

AN OVERVIEW OF THE NCI STUDY

The NCI report (with its subannexes listed on the world wide web) summarizes estimates of the thyroid dose resulting from each of 100 atmospheric tests and for the entire series of 828 underground tests. In all, approximately 150 million curies of I-131 were released to the atmosphere from the Nevada Test Site, most of it over a 5-year period (1952-1957). This is about three to four times the amount released from the Chernobyl reactor accident, about 200 times that released from Hanford, and about 5,000 times the releases at Oak Ridge, Tennessee. It is important to recognize that I-131 is only one of a number of radionuclides contained in NTS fallout. The impact of these additional radionuclides has not been addressed in the NCI report.

The NCI dose reconstruction is by far the largest and most extensive dose reconstruction ever carried out in the USA. In terms of the exposures, doses, and potential health impacts from government research and development activities, it is also the most important. Significant exposures occurred throughout the entire country, with the highest exposures being to people who were in childhood during the time of testing. Thyroid doses were estimated for several categories of individuals for each of the more than 3,000 counties in the contiguous USA. Radioactive iodine-131 from Nevada was also deposited in Canada, but to the best of my knowledge, the doses, and health impacts of NTS fallout to individuals and populations exposed beyond the border of the USA have not been addressed in any detail, by NCI or any other organization.

In spite of the large amount of information contained in the NCI report and considering the 14-year duration of the investigation, it probably received the smallest amount of financial resources compared with the costs of other dose reconstructions carried out at specific locations. The cost of this study was about one-half to about one-tenth that of similar investigations at Hanford, WA, Rocky Flats, CO, Savannah River, GA, Fernald, OH, and Oak Ridge, TN. It was but a small percentage of the cost of the major dose reconstruction performed for the US World War II veterans exposed in Nevada and in the Pacific. The funding level for the NCI study was inconsistent with its importance.

SPECIFIC FINDINGS OF THE NCI STUDY

Significant doses occurred in the mid-west and eastern USA

One of the major findings of the NCI report was the large extent of fallout that occurred in the mid-west and eastern USA. In many instances, thyroid doses to children residing in the eastern USA were equivalent to or greater than doses to children in counties near the Nevada Test Site, where residents are eligible for compensation for specific radiogenic cancers under the Radiation Exposure Compensation Act of 1990.

For example, according to information available on the NCI web site, a child born on January 1, 1952, in Clark County, Nevada, could have received a thyroid dose ranging from about 0.4 to 68 rad, with a central estimate of 5.5 rad, if his or her diet included an average amount of milk purchased from the store. A child of similar birth date and dietary habits born in Washington, DC, could have received a dose ranging from 1.2 to 21 rad with a central estimate of 5 rad. A rad is a unit of radiation energy absorbed per mass of tissue (100 erg per gram).

Average doses were highest for those in childhood at time of testing

It is estimated that the average thyroid dose for about 3.5 million children under the age of 1 during 1952 ranged from 5 to 20 rad with a central estimate of 10.3 rad. The average dose for about 14 million children who were ages 1 to 4 years old in 1952 ranged from 3.4 to 13 rad with a central estimate of 6.7 rad. The average dose for another 14 million children aged 5 to 9 years in 1952 ranged from 2.3 to 9 rad, while the average for 23.9 million children aged 10 to 19 years in 1952 ranged from 1.2 to 4.6 rad. The majority of these children resided in the more populated eastern USA.

High individual doses occurred in children who drank noncommercial sources of milk or above-average amounts of commercial milk

The age at time of exposure and the amount and type of milk consumed were important determinants of dose. For example, for children born in 1952 who consumed either above-average quantities of retail milk or milk from local sources such as from a family cow or a local farm, there were about 270 counties in the USA where central estimates of total thyroid doses could have exceeded 30 rad and nearly 2500 counties where central estimates of doses were as high as 10 to 30 rad. In contrast, for individuals on a similar diet born in early 1945, there were only 600-700 counties in which the total doses exceeded 10 rad. For individuals on a similar diet born in early 1957, thyroid doses exceeded 30 rad in 13-30 counties and 10 rad in 700-1000+ counties.

The maximum doses occurred among children who consumed goat's milk

The maximum thyroid doses would have occurred for children who, for one reason or another, consumed milk from a backyard or local farm goat. For these individuals, thyroid doses may have approached or exceeded 100 rad. High doses occur from the consumption of goat's milk because goats are much more efficient in transferring iodine to their milk than are dairy cows. In Meagher County, MT, the county with the highest dose estimates, a child born in early 1952 who consumed goat's milk is estimated to have potentially received a thyroid dose ranging from 20 to more than 5000 rad, with a central estimate of 330 rad. NCI estimates that there may have been as many as 40,000 individuals in the USA who consumed goat's milk at the time of NTS atmospheric testing, with perhaps as many as 14,000 of these consumers of goat's milk being under the age of 15 yrs.

COMPARISON WITH PROTECTIVE ACTION GUIDES, RADIATION PROTECTION STANDARDS, AND OTHER ESTABLISHED CRITERIA

To put the NCI thyroid dose estimates into perspective, they can be compared against protective action guides and radiation protection standards of the past and present.

Comparison with protective action guides

During the time of testing, the US Atomic Energy Commission was self-regulated. There were no guides applicable to exposure of the thyroid. The operational limit in 1957 was 3.9 roentgens per year or test series for whole body external gamma radiation for offsite exposure. There is evidence from 1957 testimony by Gordon Dunning that AEC was aware of the fact that doses to the thyroid of children could have been substantial, but special limits were not established.

In 1964, the Federal Radiation Council (FRC) recommended a protective action guide of 10 rad cumulative dose for a suitably homogenous sample of children under the age of 1 year. The average dose for nearly 3.5 million children under the age of 1 year at the time of testing was 10.3 rad, indicating that doses for substantial numbers of children could have exceeded the FRC's protective action guide. For children under the age of 1 year who consumed more than an average amount of milk, and for those who consumed milk from local farms, backyard cows, or goats, the doses would have been much higher than the FRC's protective action guide.

Presently, the Food and Drug Administration (FDA) protective action guides are set at 1.5 rad and 15 rad, the former being the preventive action guide (feeding of cows with uncontaminated stored feed) and the latter the emergency action guide (confiscate milk from the market before distribution). At thyroid doses of 25 rad or greater, the administration of stable iodine is recommended by EPA to block the thyroid uptake of I-131 (Appendix E-6 of the NAS/IOM report). The NCI study clearly indicates that in many locations of the USA, these dose levels could have been exceeded. The World Health Organization (WHO) is presently in the process of recommending that stable iodine be administered to a potentially exposed population when necessary to avert possible thyroid doses exceeding 1 rad in children under the age of 18 yrs. For children born in early 1952 and who consumed non-commercial sources of milk, or who consumed higher than average amounts of commercial milk, a thyroid dose of 1 rad from exposure to NTS I-131 was exceeded at virtually every location in the USA.

Comparison with radiation protection standards

Thyroid doses from fallout exposure also exceeded radiation protection guidelines of the past and present. In 1954, the NCRP recommended a dose limit for children of 1.5 rem per year for critical organs of the human body. For I-131, a rem is equivalent to a rad. Current EPA thyroid dose limits for the operation of facilities in the uranium fuel cycle are set at 0.075 rem per year (40 CFR 190). Although these dose limits are specified for a period of a year, individual exposures to NTS fallout I-131 often exceeded these limits over the time period of a single test series, the duration of which was less than a few months.

Comparison with present Superfund risk limits for maximally exposed individuals

Decisions for the consideration of remediation of contamination at Superfund sites are usually triggered when the excess lifetime risk of cancer for a maximally exposed individual exceeds one chance in ten thousand. Using risk estimates developed at Oak Ridge, Tennessee, I have estimated that a lifetime excess thyroid cancer risk of one chance in ten thousand is roughly equivalent to a thyroid dose of 0.12 to 2.8 rad, with a central estimate of 0.5 rad, for a cohort of children of mixed gender and ages from 0-15 years at time of exposure. The average thyroid dose for nearly 44 million individuals who were in the age group of 0 to 15 years in 1952 was from 1.1 to 4.4 rad, with a central estimate of 2.2 rad. Thus, the excess risk of thyroid cancer for many of these persons exceeded this one chance in ten thousand Superfund risk criterion.

Comparison with the McDonald decision (August 1998) for Hanford plaintiffs

A recent court decision (A.A. MacDonald, 1998 U.S. District Court) to determine the eligibility of plaintiffs with thyroid cancer to pursue their claims against the operators of the Hanford facility has specified a thyroid dose of 5 rad for children 0 to 4 years of age at the time of exposure. The average dose for 17,500,000 individuals who were in this age group in 1952 and exposed to NTS I-131 ranged from about 3.7 to 15 rad, with a central estimate of 7.4 rad. It is evident that a large number of individuals exposed to NTS fallout I-131 received doses that exceeded the eligibility criterion established for plaintiffs in Hanford litigation.

ESTIMATES OF HEALTH RISK FROM NTS FALLOUT

Public Law 97-414 mandated the NCI to estimate the health risk from exposure to I-131 in weapons fallout. Estimates of health risk, however, are not available in either the NCI report or on the NCI web site. The primary risk associated with exposure to I-131 in weapons fallout is the occurrence on the thyroid of radiogenic nodules that are either adenomas or carcinomas. At higher doses, non-neoplastic thyroiditis may also be induced by exposure to I-131.

Risk estimates by Dr. Charles Land, NCI

On December 19, 1997, in a presentation to the NAS/IOM, Dr. Charles Land of the NCI estimated that the total number of excess cases of thyroid cancer for those individuals in the USA who were alive in 1952 could range from 11,300 to about 212,000, with a central value of 49,000. The majority of these cases would be manifested among females who resided in the mid-west and eastern USA who were under the age of 5 at the time of the weapons tests. About 45% of these cases are expected to have already occurred, with more in females than in males.

Risk estimates by F.O. Hoffman and I.A. Apostoaei, SENES Oak Ridge, Inc.

On December 20, 1997, I made a presentation to the NAS/IOM on the risk from exposure to NTS I-131. Using the NCI average dose estimates and a Monte Carlo method for handling the propagation of uncertainty in the dose and risk calculations, I presented a range of 8,000 to 208,000 excess cases of thyroid cancer. These calculations included the uncertainty in the relative biological effectiveness of I-131 and radiogenic cancer risk coefficients developed originally for the Oak Ridge dose reconstruction study.

My present work indicates that the risk of radiogenic thyroid cancer is highest in Americans whose ethnic origin is from the Philippines and least in Americans of African ethnic origin. Females are at greater risk than males, with the risk being greatest when exposures occur in early childhood. For teenagers over the age of 15 and for adults, the risk of radiogenic thyroid cancer appears to be quite small.

Evidence for the link between I-131 exposure and thyroid cancer

For both Dr. Land's risk estimates and my estimates, the dose response was based primarily on epidemiological data for thyroid cancers resulting from childhood exposures to external radiation. Support for the use of these data comes from epidemiological investigations on children exposed to I-131 in Utah from weapons testing in Nevada, controlled animal experiments using I-131 and x-rays to irradiate the thyroids of prepubescent female rats, and epidemiological follow-up of children exposed to I-131 during the aftermath of the Chernobyl accident.

Previously, it was assumed that I-131 was much less effective than external radiation in producing thyroid cancer. These differences now seem to be explained by the strong effect of age at time of exposure. An increase in risk of thyroid cancer has not been confirmed from the millions of diagnostic applications of I-131 in medicine. However, such diagnostic treatments are seldom given to young children, the most radiosensitive subgroup of the population.

Estimates of mortality

Although thyroid cancer is highly treatable, clinical treatment usually requires surgical removal of the thyroid gland and placing the patient on synthetic thyroid hormone for life. Less than 10% of diagnosed cases of thyroid cancer will result in premature death by 20 to 30 years after treatment. This means that the radiogenic mortality induced by exposure to I-131 in NTS weapons fallout may be more than 1,000 but will likely be less than 20,000 deaths, with a central estimate of more than 4,000 deaths.

Difficulties of assessing health effects from disease registries

According to the NAS/IOM report, preliminary surveys of disease incidence and mortality registries tend to support the lower estimates of the ranges estimated by either Land or myself. However, these types of surveys give information only on the locations where the diseases have been diagnosed. They do not contain information about individual residence histories and doses. This absence of detailed information results in an inherent bias toward negative findings. Thus, the inability to confirm widespread increases of thyroid cancer in geographic disease incidence or mortality registries should not be used as evidence to refute the upper ranges of excess thyroid cancer induced by exposure to NTS fallout.

Risk of non-neoplastic thyroid disease

There is evidence that at doses extending below 100 rad, individuals may be at increased risk of autoimmune thyroiditis (pages 55 to 58 in the NAS/IOM report). For those 14,000 children exposed to NTS I-131 through consumption of goat' s milk, doses approaching and exceeding 100 rad or more may be sufficient to foster concern about this specific form of radiogenic disease.

The probability that existing disease may have been caused by one's exposure

For those in childhood (0 to 4 years) at time of exposure, thyroid doses on the order of 30 rad or more would be equivalent to an excess lifetime risk of thyroid cancer from 2 to 40 chances in one thousand, with a central estimate of nine chances in one thousand. Given this measurement for any specific individual, the chances are still very low that a disease later in life will be induced by his or her exposure. On the other hand, once this person has contracted the disease, the probability that thyroid cancer was caused by this exposure is 28 to 92%, with a central estimate of 70%. At doses of 100 rad, however, the probability of causation would be from about 60 to 97%, with a central estimate of 89%. Thus, for those exposed in early childhood who were raised on a diet of goat' s milk and who now have manifested thyroid cancer, the probability is very high that this disease was caused by that persons exposure. For the 14,000 children in the USA estimated to have been on a diet of goat' s milk at the time of atmospheric testing at NTS, I have estimated that a total of from 70 to several hundred cases of thyroid cancer will occur over the lifetime of this cohort with the majority of these due to exposure to I-131.

HAVE THE IMPORTANT FINDINGS AND THEIR SIGNIFICANCE BEEN ADEQUATELY CONVEYED TO THE PUBLIC BY NCI?

Information on exposures and doses to specific population subgroups is difficult to find

The information provided by NCI, in their report and on their web site, is not presented in a manner that will allow a member of the public to readily determine the significance of exposure to NTS fallout. Information on the magnitude of thyroid doses to those exposed in early childhood, the cohort at highest risk, is difficult to find. The report gives per capita averages and the overall collective dose to the population, but the risk of thyroid cancer is very much dependent on gender and on the age of an individual at time of exposure. The reader must go to the Appendices in Section 8 of the NCI report before an appreciation can be obtained for the importance of age and diet in determining the dose. The Appendices are also necessary to appreciate the widespread significance of potentially high doses (>30 rad) from exposure to NTS fallout. The doses to individuals consuming goat' s milk are not presented in the NCI report, but can be obtained from the NCI web site.

Estimation of health risk is not included in the NCI report

One major reason for the difficulty in public comprehension of the NCI report is that it includes no estimates of health risk, an endpoint that is more readily understood than dose. Health risks are neither discussed in the report nor on the NCI web page. I believe that the absence of information on the potential health risk in the NCI report is a major shortcoming of the study. The estimation of health risk in dose reconstruction studies has become standard practice at Rocky Flats, Oak Ridge, and Fernald.

To date, a rigorous analysis of health risk has not been performed for releases of radionuclides from the NTS. Unlike the NCI report, which focused only on I-131 in fallout, the detailed dose reconstruction within the Offsite Radiation Exposure Review Project (ORERP) directed by the US Department of Energy and completed in the early 1990s for the counties and townships near the Nevada Test Site included dose estimates for all radionuclides in NTS fallout. However, the estimation of health risk, although technically a feasible task, was precluded from the scope of the study. By contrast, the estimation of health risk to individuals and the probability of causation of specific radiogenic diseases was a Congressional mandate to DHHS and NCI within PL 97-414. Despite this mandate, the NCI report does not address the issue of the health risk to individuals from I-131 in fallout.

The NAS/IOM report concludes that the link between I-131 exposure and thyroid cancer is now confirmed as the result of investigations of children exposed to fallout from the Chernobyl accident. Last year, NCI maintained that the link between I-131 and thyroid cancer was still inconclusive. Yet those most familiar with the results of Chernobyl are the very NCI investigators responsible for the evaluations of NTS fallout. The conclusions regarding the link between I-131 and thyroid cancer in children exposed to Chernobyl fallout have not changed substantially in at least three years.

Dose is not a reliable indicator of risk

A discussion of health risk within the NCI report is critical, otherwise the full impact of weapons testing on the American people cannot be readily ascertained. Without a discussion of risk, the reader will not know that an adult male living near the Nevada Test Site at the time of testing who received a dose as high as 20 rad to the thyroid would be at ten times lower risk than a young female child living in the eastern USA and receiving a dose of merely 0.5 rad. Gender and age at time of exposure are more important determinants of risk than are dose, diet, and location.

At present, the only NCI discussion of health risk from exposure to I-131 in NTS fallout is in the memorandum of September 27, 1997, to Dr. Richard Klausner, Director of NCI, from Dr. Charles Land, NCI, and in presentations made by Dr. Land before the ACERER and before the NAS/IOM in December of 1997. These materials are not readily accessible to members of the public, although they are reproduced and discussed in the recent NAS/IOM report. These risk estimates must be expanded much further to comply with the full mandate of PL 97-414.

The NCI uncertainty analysis is inconsistent with current practice

One of the strengths of the NCI investigation was a major effort to account for all sources of uncertainty and to express uncertainty in the final estimates of thyroid dose. Unfortunately, the presence of uncertainty in the dose estimates is somewhat obscured in the presentation of results as the NCI report focuses mainly on the presentation of central (median) estimates.

In the NCI report and in the data presented on the web page, the results are presented only as a geometric mean (GM), and a geometric standard deviation (GSD). Uncertainty in the dose estimates is more readily communicated through the use of a 90 or 95% uncertainty range (confidence interval) as is now common practice for dose reconstructions at Hanford, Fernald, Rocky Flats and Oak Ridge. For example, for an individual born on January 1, 1952, in Boise, Idaho, who consumed an average diet and an average amount of milk, NCI reports a thyroid dose of 19 rad (GM) with a GSD of 3.8. Presenting the results in this manner causes the reader to focus only on the central estimate and to discard important information about uncertainty. A 95% confidence interval would show that the dose for an individual in Boise, Idaho is highly uncertain and could range from 1.4 to 260 rad.

In addition, the methodology used by NCI for the analysis of uncertainty, which requires all uncertain variables to be described as lognormal probability distributions, reflects practices of the early to mid 1980s. Current dose reconstructions, facilitated by advances in software during the late 1980s and early 1990s, use computer algorithms (employing Monte Carlo simulation) that free the analyst from the restrictive assumptions required by the NCI methodology. These more recent approaches also allow uncertainty due to incomplete information to be separated from information about inter-individual variability. The NCI methodology makes no distinction between these separate sources of uncertainty.

Scientific notation in 'E' format is confusing to the lay public

Another impediment to public comprehension of the results is the fact that on the NCI web site, dose values are presented in scientific notation in 'E' format (e.g., 3E+2 for 300). Scientific notation is a convention readily understood by engineers and scientists, but read only with extreme difficulty by individuals who are not technically trained. A major effort is still required to make the materials on the NCI web page accessible and transparent to members of the public seeking to understand the significance of exposure to NTS fallout.

OPENNESS IS ESSENTIAL WHEN PUBLIC CREDIBILITY IS AT STAKE

In all present dose reconstruction studies directed by the Centers for Disease Control or by State Departments of Health, there is a major commitment to achieving credibility with the public. Affected communities are particularly concerned about the integrity of government-sponsored dose reconstructions because their exposures were involuntary and caused by government decisions made without their consent or knowledge.

There is an inevitable suspicion among members of affected communities that the government continues to harbor incentives to minimize the perceived severity of the potential impact of radiation exposure on public health. Therefore, an essential prerequisite for trust building with the public is a strong institutional commitment of openness and outreach to members of the affected community.

The NCI study was not open

Over the 14 years of the study, it is not evident that NCI took initiative on its own to communicate with the public nor to disclose preliminary results in a manner that would allow the interpretation of the potential health significance of their findings. Unlike other dose reconstructions, the advisory committee to NCI included no members of the affected community. In fact, some members of the advisory committee eventually assumed the role of study participant and co-author. Unlike other federal advisory committees, the chair was also the NCI project director.

To the best of my knowledge, the basic results of this study were known in 1989. By 1992, major portions of the final draft report were completed, but the actual report was not released until October 1997.

Numerous scientific presentations made by NCI

During the late 1980s and early 1990s, numerous scientific presentations and publications were made by the principal authors of the NCI study at national and international conferences. These presentations and publications presented details of the methodology, the results of intermediate calculations, and information about gross per capita average doses and collective population doses. With the exception of the counties near the Nevada Test Site, I am not aware of any presentations by NCI that indicated how high doses could be for individuals exposed in childhood who consumed higher than average amounts of milk, nor what the magnitude of doses for each county would be for children on a diet of fresh milk who resided in the heavily populated eastern USA. I recall one presentation given in Vienna that showed a map of per capita doses throughout the entire USA, but this map was later omitted from the published report.

Of the cases of thyroid cancer induced by exposure to NTS fallout, most will occur in females who were under the age of 5 at time of exposure and who resided in the mid-west and eastern USA. I am not aware of any NCI publication or presentation that has revealed this important conclusion. Emphasis in the NCI presentations was typically placed on the overall collective dose to the entire population, a concept frequently used by specialists in health physics, but of limited utility for estimating the risk to the population from exposure to I-131. The population risk is controlled, not by the average or overall collective dose, but by the doses received by young children (most of whom would be less than 5 years old at the time of exposure).

A policy of openness would have assured prompt release of results

I sincerely believe that if this study had adopted a policy of openness and public outreach, the release of the NCI report would not have taken 4 to 5 years from the time of completion of the final calculations. Furthermore, I believe that if this study had solicited public involvement, the NCI report would contain information on individual health risk as mandated by Congress. Preliminary disclosure of its results in 1989 would have also prepared other public health organizations to coordinate a strategy for a timely response to assist those exposed and concerned. This important task instead was transferred to the NAS/IOM, whose volunteer members were required at the close of 1997 to produce a definitive report in less than 9 months. I believe that the work undertaken by the NAS/IOM in 1997 should actually have been initiated by NCI as early as 1989.

Recommendations to encourage openness in the NCI study

In about 1990, as the result of a positive experience I received as a member of the Health Advisory Panel for the Colorado State Department of Health at Rocky Flats, I personally called the NCI project director and suggested that he consider opening the NCI study up to representatives of the public. I suggested that NCI consider a series of public workshops. At the time I was told that such a procedure, although certainly desirable, would not be practical. The study was nearly completed, and it would be difficult to identify representative members of affected groups. I raised this issue with the project director again in 1994 and again in April of 1997.

NCI was informed in early 1996 about risks from NTS fallout in Tennessee

In 1994 I became involved in dose reconstruction efforts at Oak Ridge, Tennessee. Since the primary contaminant of concern was I-131 released from 1944 to 1956, I was interested in estimating the potential confounding influence of NTS I-131 that was deposited in this region from 1952 to 1957. At this time I recommended to the Tennessee Department of Health that the NCI be formally requested to advise and assist us in our investigation of the Oak Ridge dose reconstruction work. In April of 1996, our first estimates of the health risk of NTS fallout I-131 in the vicinity of Oak Ridge, Tennessee were completed after receipt of electronic files from NCI on their calculations of the deposition and milk concentrations of fallout I-131 in each county of Tennessee.

We estimated that the excess lifetime risk of thyroid cancer for a female child born in 1951 could range from a few cases in ten thousand to more than one case in one hundred exposed individuals, depending on the source of fresh milk. These estimates were moderately uncertain, with confidence bounds being a little more than a factor of ten on either side of the central value. Our estimates of thyroid doses were less uncertain with central estimates ranging from 2.5 to 63 rad, depending on the source of milk in the diet.

Recognizing the potential importance of this information, I faxed these results to NCI for comment and review. We received no reply. I later sent a copy of the full draft report; still we received no response about the significance of the dose and risk estimates. About six months after the NCI report itself was published, a revised draft report of the Oak Ridge Dose Reconstruction was completed in March 1998 and forwarded to NCI. This time we received extensive and thorough review comments on our work from NCI.

IS FOLLOW-UP NEEDED TO BROADEN THE INTENT OF PL 97-414?

In presenting this testimony, I feel compelled to note to Congress that if its intent was to investigate the full extent of public health outcomes from exposure to NTS fallout, then it is important to proceed to investigate the exposure to all radionuclides in fallout and to evaluate potential health impacts to individuals residing beyond the continental borders of the USA.

Such an analysis would have been readily accomplished by the NCI because the techniques developed to estimate I-131 depositions from the analysis of gummed paper are the same ones required to estimate depositions for all of the other radionuclides in NTS fallout. Some of the radionuclides from NTS weapons testing, such as strontium-90, cesium-137, and plutonium-239/240 are still in soil and in present-day food products. Although PL 97-414 restricted NCI to the investigation of I-131, NCI made no attempt to request that the scope of its study be broadened so that it could evaluate the full public health consequences of NTS testing of nuclear weapons.

CONCLUDING REMARKS

I have had numerous occasions to reflect back on my experience with the NCI study and its investigators since my initial involvement in 1987. Based on a collection of experiences, I now believe that prior to October 1997, there was concern within NCI about the negative impact that its study might have on public perception about the legacy of atmospheric testing of nuclear devices at the Nevada Test Site. I believe that this concern may have been partially responsible for the delay in publication of the results and the omission of risk estimates. An NCI commitment to openness would have ensured that issues relevant to public health and the public right to know were addressed. A commitment to openness would have meant that the advisory committee to NCI would have included representatives of the affected community as well as independent scientists familiar with the conduct of dose reconstruction; and, of course, the Director of the NCI study would have never have been Chairman of his own "Advisory Group." Further, this advisory group would have operated under the rules of the Federal Advisory Committee Act. Openness fosters increased transparency in oral and written communication and provides incentives for investigators to reach out beyond their traditional peers of health physicists, biostatisticians, and epidemiologists. I believe that even the recent NAS/IOM report could have been improved through a more aggressive institutional commitment to openness. Furthermore, the delay in release of the NCI report would not have occurred had NCI made a commitment to openness and had NCI provided opportunities for involvement by members of affected communities.

I hope that one outcome of this hearing will be to implement needed improvements in the conduct of public health research as carried out by all branches of the federal government. This concludes my testimony this morning, and I am now willing to answer any questions you may have.

Thank you.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

Testimony of

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Public Health Service

U. S. Department of Health and Human Services

Before the

Permanent Subcommittee on Investigations

Committee on Governmental Affairs

United States Senate

September 16, 1998

Good morning. I am Barry Johnson, PhD, Assistant Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR). I am accompanied by Jeffrey Lybarger, MD, Director, Division of Health Studies, ATSDR.

Our testimony today will address ATSDR's health surveillance responsibilities under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as Superfund. In particular, we will describe ATSDR's finding that health surveillance of persons exposed to radioactive iodine released, in the past, from the Hanford nuclear facility in Richland, Washington is called for under CERCLA. Our testimony also relates the public health approach taken by ATSDR in considering CERCLA's health surveillance provisions when populations have been exposed to hazardous substances released into the environment. In view of the recent recommendation of the National Academy of Sciences's Institute of Medicine (IOM/NAS) against thyroid cancer screening, we will also highlight our differences in decision making and why we continue to support our decision for a medical monitoring program for a subpopulation of persons exposed as children to iodine-131 released from the Hanford facility.

Health Surveillance under CERCLA

As background, ATSDR was created by Congress to address the public health implications of hazardous waste sites and unplanned releases of hazardous substances into community environments. ATSDR works closely with the U.S. Environmental Protection Agency (EPA), other federal agencies, states, communities, and tribal nations in the conduct of our CERCLA responsibilities.

ATSDR's public health responsibilities under CERCLA include conducting public health assessments and attendant activities at all sites on the National Priorities List (NPL). There are four NPL sites at the Hanford nuclear facility. ATSDR was led to consider health surveillance of Hanford populations through our evaluation of environmental contamination data provided to us by the Department of Energy (DOE) and state agencies, as well as findings from the Hanford Environmental Dose Reconstruction project. Based primarily on consumption of milk contaminated with iodine-131, thyroid dose estimates were highest for young children during the period, 1945 through 1951. The dose reconstruction findings were prepared for the Centers for Disease Control and Prevention (CDC) and published in 1994.

With regard to ATSDR's mandated responsibility for health surveillance, CERCLA [42 USC 9604,§104(i)(9)] states, in part,

> *Where the Administrator of ATSDR has determined that there is a significant increased risk of adverse health effects in humans from exposure to hazardous substances based on the results of a health assessment, an epidemiologic study, or an exposure registry, and the Administrator of ATSDR has determined that such exposure is the result of a release from a*

facility, the Administrator of ATSDR shall initiate a health surveillance program for such population. This program shall include but not be limited to (A) periodic medical testing where appropriate of population subgroups to screen for diseases for which the population or subgroup is at significant increased risk, and (B) a mechanism to refer for treatment those individuals within such population who are screened positive for such diseases.

ATSDR's Medical Monitoring Program

ATSDR interprets the cited statutory language as an important public health intervention strategy that provides early diagnostic and referral services for a well-defined population at health risk. Early detection of a change in health status is the most effective way to lessen the burden of more advanced disease and enhances survival. ATSDR's public health approach for considering a population for health surveillance involves a rigorous process that

- applies established medical monitoring criteria that were adopted by ATSDR following intensive public and technical review[2] to determine if monitoring is appropriate under the CERCLA provisions appropriate for that population;
- uses a multidisciplined panel of experts to apply the criteria for medical monitoring and consider the merits and specific components of the program for a specific site;
- establishes the means and supports public involvement in decision making at every stage;
- assures independent and external peer review of all matters of science and public

health practice;

- builds support and involvement of affected stakeholders, e.g., state and local health departments, affected citizens, Native American tribes, and others;
- reviews the public health policy implications, scientific evidence, and program risks and benefits as part of a formal agency approval process;
- implements health surveillance activities when indicated; and
- periodically evaluates the health surveillance program for effectiveness and quality.

ATSDR used this approach to determine that medical monitoring for thyroid diseases is needed for some persons exposed as children to historical releases of radioactive iodine from the Hanford nuclear facility. For purposes of this testimony, we use the terms medical monitoring and health surveillance interchangeably.

Development of the Hanford Medical Monitoring Program

In February 1997, ATSDR concluded its determination that a medical monitoring program was warranted for persons at significant increased risk of thyroid cancer and other conditions from exposure to iodine-131 released from the Hanford Nuclear Reservation during the period, 1945 through 1951. In south central Washington State, the Hanford facility produced the plutonium used in American nuclear weapons. During a chemical separations process, primarily during 1945, iodine-131 was released to the atmosphere. As previously mentioned, a dose reconstruction study documented large releases of iodine-131 into the atmosphere and provided dose estimates of representative individuals according to their age and where and when they lived within a large geographic area surrounding Hanford. ATSDR determined that the major public health risk is among young children downwind of the facility who consumed contaminated milk during the period, 1945 through 1951.

In order to make the public health decision about Hanford, ATSDR used its medical monitoring criteria to determine the appropriateness of health surveillance of thyroid disease for persons exposed to radioactive iodine released from the Hanford facility. A summary of the seven criteria is provided as an attachment. They were developed with input from the public and technical experts and endorsed by ATSDR's Board of Scientific Counselors. In applying the criteria to Hanford, ATSDR used a review process that involved a variety of experts, as well as several representatives of the community and tribal populations impacted. In particular, ATSDR and CDC jointly formed the Hanford Health Effects Subcommittee (HHES) to advise the agencies on their research and public health activities related to the Hanford facility. ATSDR and CDC also worked closely with the Intertribal Council on Hanford Health Projects, which included representation from 9 tribal nations in the Hanford region. The HHES provided an essential resource for expressing health concerns from communities and tribal nations. They reviewed ATSDR's approach to, and findings from, the consideration of a medical monitoring program.

We will briefly discuss several key points related to the medical monitoring decision for persons exposed to radioactive iodine released from the Hanford nuclear facility. ATSDR has published an extensive report that provides important background and details of the medical monitoring program associated with the Hanford nuclear facility$_3$. We can make these documents available to the subcommittee, if that would be of assistance.

Exposure and Related Health Outcomes - As stated in this testimony, CERCLA directs the Administrator of ATSDR to initiate a health surveillance program for populations at significant increased risk of adverse health effects as a result of exposure to hazardous substances released from a facility. The law further defines this program as a periodic medical testing to screen people at significant increased risk for disease. From our expert panel we determined that a median 10 rad, or higher, thyroid dose estimate for children would place these individuals at significant increased risk. This is based on the extensive medical literature of external radiation exposures that support elevated thyroid cancer risks at this dose level, or higher, among children. These elevated thyroid cancer risks occur for many decades (at least 40 years or more) following radiation exposures to the head and neck in childhood. The literature also suggests that there are other health outcomes that might be related to thyroid radiation exposures, including hypothyroidism, chronic lymphocytic thyroiditis, and hyperparathyroidism. Moreover, there is an increasing amount of medical literature that supports a reasonable association between radioactive iodine exposures and excess occurrences of thyroid neoplasms. This literature includes published studies of populations exposed to the Chernobyl reactor fire in 1986, Marshall Islanders exposed to the 1954 BRAVO test releases, and schoolchildren exposed to Nevada Test Site atmospheric testing releases during the period, 1951 through 1962.

Target Population - One of the ATSDR's medical monitoring criteria requires a well-defined, identifiable population at-risk with sufficient levels of exposure. The Hanford dose reconstruction study conducted for CDC assisted ATSDR in defining an eligible population. The thyroid dose estimates for Hanford were determined for 6-mile by 6-mile grids within a 75,000 square mile region around Hanford. ATSDR estimates that 14,000 people (majority were exposed in 1945) would have received a sufficient thyroid dose as children to place them at significant risk of thyroid cancer and other thyroid and parathyroid conditions. ATSDR will be able to locate these individuals by various methods using birth certificates, contacting ongoing and previous study participants, and other tracing methods. Our tracing efforts of historical residents for other ATSDR studies have successfully located 85% or more of the eligible population. In addition, CDC has traced and located over 85% of their Hanford thyroid morbidity study participants who were young children at the time of exposure.

If the entire eligible population participates in the program, ATSDR estimates that 90 thyroid cancers will be detected through the first round of the medical monitoring program, versus eight thyroid cancers that would be expected without such a program. From our review of the scientific and medical literature, there is evidence that suggests early detection and treatment of thyroid disease can save lives, reduce chronic health conditions, and lessen the chance of thyroid cancer recurrence.

Prevention Effectiveness Approach - Because there is no randomized controlled study proving the benefits of thyroid cancer screening, ATSDR conducted a prevention effectiveness analysis to project the potential harms and benefits of a program based on a clinical decision model. The model used program scenarios with different eligible populations and methods of medical evaluation and compared the findings to a no-program scenario. The model generated estimates of the number of thyroid nodules, biopsies, surgeries, thyroid cancers, and thyroid cancer deaths averted for each scenario. The analysis helped determine which population subgroups and methods of medical evaluation would result in the most benefits and fewest harms to those who might participate in a medical monitoring program. Prevention effectiveness analysis helped identify a well-defined, high risk population that could benefit from a program. Using a range of thyroid dose estimates, the analysis showed medical monitoring of persons having thyroid dose estimates of 10 rad or greater as children would yield a higher rate of thyroid cancers detected early and lives saved. The analysis also showed that extending the more precise geographic region of program eligibility to county boundaries resulted in large numbers of lower risk people (with lower thyroid dose estimates) being evaluated and being put at greater risk of harm and false positive diagnoses. The prevention effectiveness analysis also allowed us to project which benefits and harms might result from various medical monitoring program scenarios. Clearly, a well-defined high risk population must be identified for a program with thyroid evaluation to derive the most benefit. The geographic precision of the radiation dose estimates from Hanford releases was a key in ATSDR's prevention effectiveness analysis and helped clearly define the at-risk target population.

ATSDR Review Process - After 18 months of careful consideration and analysis, the ATSDR proposed program underwent an extensive review process using interagency technical reviews (CDC and ATSDR), external scientific peer reviews (included four experts in clinical endocrinology, occupational and environmental medicine, disease prevention services, and preventive medicine and community health), comments from the public, and a senior and executive management public health science and policy review. The review process strengthened our finding that the program has genuine merit (for a well-defined high risk population) and should be implemented under our CERCLA responsibilities. Following meetings with executive and senior scientific staff and a meeting with community and tribal representatives, Dr. David Satcher, as the former ATSDR Administrator and Director of the CDC, signed the decision memo on February 7, 1997 to implement the program, pending funding from the DOE.

Differences in Decision Making

ATSDR is directed under CERCLA to perform health surveillance programs for populations at significant risk of adverse health effects from exposure to hazardous substances. This represents a different type of public health activity than the setting of national policy or standards for thyroid cancer screening.

We perform our work on a site-specific basis using the best available scientific and medical information and following a rigorous process that is based on our seven criteria for medical monitoring. We not only involve the affected public in our decision making process, but also conduct external scientific peer review of our work to make the best *public health* decision possible. By consulting recognized experts in the medical issue under consideration and involving the public most directly affected by the proposed intervention, this process provides an important and necessary balance for public health decision-making.

Because we are not setting national screening policy, our criteria do not require a randomized controlled study showing the benefits of screening. The expectation of such evidence by IOM is understandable, especially for a national screening policy. However, for ATSDR's targeted medical monitoring of a well-defined, high risk population we took the approach of using a weight-of-evidence. Such a screening approach is typically used in public health programs, for example lead screening for children. Virtually all public health experts would agree that lead screening programs in communities known to have high contaminations of lead have resulted in early detection and treatment of lead poisoning in our children. We believe that a targeted thyroid screening program for people at lifelong risk from Hanford exposures will derive similar benefits. ATSDR will conduct ongoing evaluations of its program to assess risks and harms -- including an expert panel review prior to initiating any medical monitoring activities -- in addition to determining how many thyroid conditions are diagnosed and treated.

We agree with the IOM/NAS that the current dose estimates for U.S. counties have large uncertainties, which makes it difficult to readily determine who was at highest risk. Other approaches might help define the highest risk population, for example a focus on young children who drank goats' milk in certain regions of the country during the release period. At Hanford, however, we are fortunate that the dose reconstruction study estimated doses at a much more precise level of geographic resolution (6-mile by 6-mile areas) and our eligible population includes 60% who received thyroid dose estimates of 25 rad or higher. Based on our ability to clearly define and locate the high risk population, our decision for medical monitoring is appropriate from a public health practice perspective.

Summary

As a final note, ATSDR successfully implemented a screening program for persons exposed to a human bladder carcinogen. This was initiated more than 10 years ago, based on the known science at the time, and on good public health practice.

In 1986, ATSDR funded its first such program for former workers at the Drake Chemical site in Pennsylvania. These former workers had been exposed to betanaphthylamine—a known human carcinogen, specifically linked to bladder cancer. A total of 364 workers were initially eligible for screening; 82% of whom chose to participate. Compliance continues to be high with participation rates ranging between 82% to 92%. Of the workers screened in the first phase, 50 have been referred for the second phase which includes a laboratory diagnostic work-up (a cystoscopy). As of 1997, two workers have been diagnosed as having early stage cancer, another 13 were diagnosed with varying degrees of dysplasia, and 25 had some type of bladder abnormality diagnosed. This program has clearly been of benefit for detection and treatment of disease for these workers, and has been so successful that it now is continued by the state of Pennsylvania.

Our testimony today has described ATSDR's health surveillance responsibilities under CERCLA. We have presented our agency's findings that medical monitoring for thyroid disease is required for persons who were exposed as children to Hanford iodine-131 releases and received sufficiently high thyroid doses. ATSDR considers medical monitoring of a well-defined high risk population to be consistent with the central principle of public health: prevention of disease is preferable to treatment and medical care, and early loss of life. Furthermore, we believe that ATSDR's mandate under Superfund carries a clear responsibility to deal with exposures of children to iodine-131 releases from Hanford during the period, 1945 through 1951, and provide medical evaluation that can lead to early detection and mitigation of disease. Our proposed medical monitoring program at Hanford is based upon the best available science, and we believe it represents sound public health policy decision made almost 2 years ago.

Mr. Chairman, we would be pleased to answer any questions that you or subcommittee members may have.

References:

(1) Farris WT, Napier BA, Ikenberry TA, Simpson JC, Shipler DB. Atmospheric pathway dosimetry report, 1944-1992. Richland (WA): Battelle Pacific Northwest Laboratories, April 1994.

(2) ATSDR's final criteria for determining the appropriateness of a medical monitoring program under CERCLA. Federal Register 1995, July; 60(145):38840-4.

(3) Agency for Toxic Substances and Disease Registry. Hanford medical monitoring program: background consideration document and ATSDR decision. Atlanta (GA): US Department of Health and Human Services, July 1997.

Attachment

Summary of ATSDR's Criteria for Medical Monitoring

(Federal Register, July 1995; 60(145):38840-4)

Medical monitoring is periodic medical testing to screen persons at significant increased risk for disease. All seven criteria must be met before a program is recommended.

☐ Evidence of exposure at a sufficient level of risk is documented.
☐ A well-defined population is at risk.
☐ A scientific basis exists for an association between exposure and health effects.
☐ The health effects are detectable and amenable to prevention/intervention.
☐ Medical screening requirements should be satisfied.
☐ Accepted treatment/intervention exists and a referral system is available.
☐ Logistics must be resolved prior to program implementation.

For Release Upon Delivery

Statement
Richard D. Klausner, M.D.
Director, National Cancer Institute
National Institutes of Health
Department of Health and Human Services
on
NCI Management of Radiation Studies

Before the
Senate Committee on Governmental Affairs
Permanent Subcommittee on Investigations
September 16, 1998

Good morning, madame chairman, and members of the Subcommittee. I am Richard Klausner, Director of the National Cancer Institute (NCI). I am pleased to testify before you today about NCI's role in radiation research, specifically about studies of exposure to Iodine 131 and its relationship to thyroid cancer. In my testimony I will describe NCI's mission, the process for scientific discovery, the management of complex scientific studies, the NCI study of I-131 exposures, our role in studies associated with the aftermath of the Chornobyl accident, and actions I have taken to strengthen oversight, management, and communication of NCI's radiation studies.

Introduction

The National Cancer Institute has a long and distinguished history in radiation research including studies of how radiation is involved in the causes of cancer and how it is used most effectively in the treatment of cancer. Today, NCI is staffed with several of the world's leaders in the field of radiation epidemiology and radiation dosimetry. When Public Law 97-414 instructed the Department of Health and Human Services to estimate the thyroid doses of iodine-131 received by people exposed to fall-out from the Nevada nuclear tests, NCI was asked to take on this responsibility. In October 1997, I testified before the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education and presented the results of that study. Following that hearing, and at the request of the Department of Health and Human Services (DHHS), the National Academy of Sciences (NAS) and Institute of Medicine (IOM) reviewed the data and prepared a report entitled "Exposure of the American People to Iodine-131 from Nevada Nuclear-Bomb Tests: Review of the National Cancer Institute Report and Public Health Implications." Their report focused on (1) assessing the soundness of the NCI analyses and estimates including those developed separately from the main report, (2) the risk of thyroid disease from iodine-131 fallout, (3) evaluating the benefits and harms of recommending a program of routine screening for thyroid cancer, and (4) identifying strategies for communicating with the public about risks and responses. We are in the process of carefully studying the report, findings, and recommendations and are working with the Department of Health and Human Services and the Centers for Disease Control and Prevention and its Advisory Committee on Energy Related Epidemiologic Research (ACERER) to implement their advice most effectively.

In April of 1986, a nuclear reactor accident took place at Chornobyl in Ukraine. Following the accident, large numbers of people were exposed to iodine-131 and, for many of them, actual measurements were made of radioactivity in their thyroid glands. With the availability of such measurements, the Department of Energy (DOE) felt that if a study of the exposed children in Ukraine and Belarus could be designed and implemented, it might be extremely valuable for determining the risk of thyroid cancer as a function of the dose of iodine-131 received. Because of NCI's experience and expertise in this field, in 1990 the DOE asked the NCI to take responsibility for planning and working with scientists of the then Soviet Union to develop long-term studies of health effects, specifically in the thyroid, that might result from exposure to I-131 from the Chornobyl accident. DOE asked that Dr. Bruce Wachholz, the Chief of our Radiation Effects Branch, manage the scientific aspects of the program. We were pleased to be able to actively participate in this study, because of the unique opportunity this tragic accident afforded us to complete the risk assessment of I-131 and thyroid cancer that was called for in P.L. 97-414. I will discuss this study in greater detail later in my testimony. Shortly after this request, the dissolution of the Soviet Union took place, and we have subsequently been working with the new independent governments in Belarus and Ukraine. In close cooperation with scientific colleagues in Belarus and Ukraine, a U.S. working group has worked with comparable working groups in each country to develop research protocols for studies of thyroid cancer in large cohorts of children and adolescents in both countries. These studies are now in progress.

NCI's Mission

The ultimate goal of the National Cancer Institute is to prevent or cure cancer. The United States Congress in 1937 established the National Cancer Institute and in 1971 reaffirmed its commitment to cancer research with the passage of the National Cancer Act. Today, as we approach the 21st century, we can take pride in our accomplishments, but our pride is tempered by the knowledge that we still have much to do to achieve our goal.

We have reached a turning point in our fight against cancer. Between 1991 and 1995, the cancer death rate and the incidence rate showed their first sustained drop since record keeping began in the 1930s. For several types of cancer - children's cancers, breast, colon and rectal, Hodgkin's and testicular - the decreasing death rates reflect cumulative research successes over the past several decades. Continued advances in our knowledge base have been a vital component in the recent decline in the cancer death rate - a decline that has translated into thousands of lives saved. However, while the decline in the cancer death rate is evidence of our successes and reflects the collective knowledge and technical advances achieved, we still face an enormous challenge to more fully grasp the underlying causes of cancer - an understanding that is the keystone of further progress. Our success will continue to be measured in terms of fewer deaths, fewer new cases, increased life expectancy, and improved quality of life for cancer survivors. Our goal of a reduced cancer burden can only be achieved through continued expansion of our knowledge base that supports the successful translation of discoveries into treatments that benefit all people who are at risk for and who have cancer.

Clinical Studies in an International Setting

The NCI is an institution of science, and our operations are driven by the processes of science. The culture of science is one of continued questioning, testing of hypotheses against evidence, critique by peers, validation of research results, and modification and extension of results as new findings emerge from the community of researchers. In this culture the pursuit of new knowledge must be the primary goal.

Importantly, much scientific research is conducted in a collaborative manner. Complex projects require the collective wisdom of multidisciplinary teams of experts and are never performed by individuals working in isolation. Members of these research teams provide the diverse and broad expertise that is necessary to ask and answer major questions relating to human health. International collaborations are particularly challenging. Culture, local customs, and language differences must be surmounted; administrative, legal, and logistical barriers overcome; and effective communication and trust established before the collaboration can even address its scientific goals.

Complementing scientific excellence, we must also have scientific and administrative mechanisms that provide oversight and accountability to our research projects and programs. Oversight of NCI activities is provided by various groups, including the Presidentially-appointed National Cancer Advisory Board, the Board of Scientific Counselors (for intramural research, conducted by NCI staff), and the Board of Scientific Advisors (for extramural research). In addition, certain individual projects, such as major clinical studies, often require specific oversight, in the form of data monitoring committees or advisory groups. These committees, functioning independently of those directly involved in the project, protect the interests of the people participating in the research and provide advice to project leaders on the future conduct of the study. They are integral to safeguarding the scientific integrity and ethical foundations of major clinical studies. Thus, it is crucial that the administrative and procedural requirements associated with clinical research serve the needs of the particular project and, in essence, be tailored to them.

The Chornobyl experience shows much about the complexity of organizing and conducting a major clinical research study in an evolving and fluid international context. This study is a comprehensive clinical epidemiologic investigation requiring an effective integration of scientific, ethical, legal and regulatory requirements in a highly volatile political environment. The project directors are Ukrainian and Belarussian scientists, and they are studying the incidence of thyroid cancer in residents of these two countries who were exposed to radiation from the Chornobyl disaster. U.S. contributions include scientific expertise, guidance, training, advice, equipment and supplies, and partial funding.

Clinical studies conducted in the U.S. must adhere to the highest ethical standards and must guarantee that patients and subjects are fully informed of the potential risks and benefits of their participation in the study. In this country, we have policies and procedures, based in law and regulation, to ensure that all clinical studies satisfy these requirements. Approval and oversight for research protocols are vested in Institutional Review Boards (IRB) in each research center involved in such studies, whether in the U.S. or abroad, which are responsible for ensuring the ethical conduct of the study. In other countries, these processes often are not as well defined; sometimes they are actually non-existent and must be established before a clinical study can start. In newly democratic countries, the concept of voluntary participation in a government-sponsored study is not always clearly understood, either by the sponsors or by the participants. In the case of U.S. involvement in the Chornobyl studies being conducted by scientists in Ukraine and Belarus, as in other foreign countries where we are working, all of the regulations and procedures that apply to clinical research in the U.S. must be followed, and we therefore had to educate our foreign collaborators, as necessary, on these processes. Our ability to effectively accomplish this training had a direct impact on project implementation and execution, effective management of protocol benchmarks, and realistic achievement of proposed study outcomes.

Additionally, effective international cooperation requires significant lead time for establishing the critical interpersonal relationships needed to work together effectively and surmount the barriers already noted. NCI staff and their foreign partners have successfully established these relationships, which now constitute a firm basis for moving forward with the Chornobyl investigations.

Management

This committee has asked about how NCI manages its research programs, with particular focus on radiation studies. My understanding of the questions and concerns directed toward NCI is that they focus on oversight and management of the Chornobyl study, rather than the scientific questions being asked. With the Chornobyl project, the management approach must and does reflect the inherent characteristics of this type of a comprehensive, complex clinical study. It is designed to respond to changing parameters that require flexibility to address myriad issues that will inevitably arise purely because of the nature of the study itself. In our large, complex clinical trials, we often use a team approach to address specific problems as they arise, while at the same time providing for proper oversight that is removed from the day-to-day operations. Decisions are generally made by consensus, and we draw the necessary pool of talent, expertise, and experienced individuals in building these teams. Collective oversight may look sloppy or chaotic to those who are used to a simpler, more defined, hierarchical management structure, but past experience has proven that this process works. The aforementioned model has been applied to the Chornobyl studies in Belarus and Ukraine, although it is important to emphasize once again that we are not running these studies. We are cooperating with the scientists and physicians in those countries who are responsible for carrying them out. We provide guidance, financial assistance, training, and other assistance, but ultimately one must remember that we cannot and should not be making unilateral decisions. As I mentioned previously, the complexity of doing a large clinical study is further complicated by the many cultural, economic, political, and fiscal challenges of working in these countries.

It may be helpful to try to explain why the involvement of real people in clinical studies poses such challenges. Our "management" plan for a clinical study is the clinical research protocol. Among other things, a clinical research protocol defines the patient accrual rate necessary to achieve numbers that will support the rigorous statistical analysis needed to substantiate a finding. We know from years of experience that a certain number of patients will drop out of a study, will be unable to complete the intervention, or that we will be unable to enter sufficient patients on the study because of an inability to obtain a sufficient supply of a drug, or due to a lack of interest among the cancer community for the particular study. One example of a clinical trial that has presented major obstacles is bone marrow transplantation, where the wide availability.of this technology as routine patient care has greatly reduced our ability to attract patient volunteers into a research setting. Protocols have been in place for years that attempt to compare existing treatment approaches to state of the art therapy; but because the study design requires that patients be randomly assigned to one treatment arm or the other, we have not been able to enter sufficient numbers of patients onto the study. When treatments are offered outside a research setting, patients don't have to risk randomization - they can simply choose whether or not to receive bone marrow transplantation. Does that mean we should give up trying to get an answer? Absolutely not. But delayed patient accrual has forced us to drastically alter our projections as to how long it will take us to complete this incredibly important study. Therefore, it is critical to understand the impact that patient accrual and follow-up has on the conduct of even the most simple clinical study, and why the management of the study must be flexible enough to accommodate such events.

The I-131 Study: Estimating Exposure to Fallout

In late 1982, Congress enacted a requirement, as part of the Orphan Drug Act (P.L. 97-414), that the Secretary of the Department of Health and Human Services undertake three studies: 1) to conduct scientific research and prepare the analysis necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131; 2) to develop valid and credible methods to estimate the thyroid doses of I-131 that are received by individuals from nuclear bomb fallout; and 3) to develop valid and credible estimates of the exposure to I-131 that the American people received from the Nevada atmospheric nuclear bomb tests. Parts 2 and 3 were addressed in a report released last year by NCI. The first part of the mandate is still the subject of ongoing research, and I will come back to this point a little later in my testimony. However, I would like to point out that this legislation was very specific in its charge to "...conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131."

Almost one year ago, I appeared before the Senate Appropriations Subcommittee on Labor, Health and Human Services and Related Agencies to deliver to Congress the long-awaited NCI report, "Estimated Exposures and Thyroid Doses Received by the American People from Iodine-131 in Fallout Following Nevada Atmospheric Nuclear Bomb Tests." Because this committee has also expressed interest in many of the same issues that were raised last year, I have appended to this statement last year's testimony and ask that it be entered into the hearing record. I said last year, and I will repeat before you today, that a more clear, more rapid, and more aggressive plan for dissemination of the results to the public was called for. That said, I also believe the dissemination we made was unprecedented for a study of this magnitude and complexity. Further, we were able to take advantage of a new technology, the Internet, to provide access to over 100,000 pages of data that would otherwise have been inaccessible to most individuals.

As I also stated last year, this delay in publication did not have an adverse impact on public health, a position reaffirmed recently by the Institute of Medicine (IOM) in the report issued on this topic September 1. As I mentioned in my testimony last year, DHHS had requested that the IOM undertake a review of the findings in NCI's I-131 report and that it make recommendations on appropriate public health measures. To carry out this evaluation, the IOM assembled two groups of expert scientists, clinicians, public health representatives and members of the public, and after several months of open meetings, committee deliberations, and consultation with other experts in many scientific and medical disciplines, released their findings and recommendations. I was impressed with the thoroughness and completeness of their process, the clarity of the recommendations, and the recognition of and sensitivity toward the need for better ways to communicate information about radiation risk to the public. This latter point is probably the most daunting challenge we face as a federal entity: how to provide complex information to the public in a clear, relevant, and understandable way. We at NCI face this challenge repeatedly. For example, many women, even those without any risk factors, fear that they will develop and die from breast cancer. However, most women don't know that more women die from lung cancer than breast cancer, and even more women die from heart disease than either of these two cancers. Environmental exposures, such as pesticides, radon, and others that are involuntary, are often viewed as being more hazardous than voluntary exposures that we often don't even think about as being hazardous. One of the IOM recommendations was that the Department of Health and Human Services undertake the research necessary to determine how to most effectively present information about risk so that it will be better understood by the public. I agree that this is a most worthwhile endeavor, and what is learned will almost certainly be of assistance to NCI in communicating to the public about cancer risk in general.

Chornobyl

I would like to return to the first portion of the Congressional mandate regarding research related to the risk of developing thyroid cancer as a result of exposure to I-131. The best way to determine the link between exposure to I-131 and the development of thyroid cancer is to actually find people who have been exposed and monitor their health. In the scientific literature, it has long been questioned whether exposure to I-131 leads to thyroid cancer. It was not until the early 1990s, in the aftermath of the Chornobyl accident, that notable increases in cancers began to be reported. Even after these reports began to appear, however, we still did not know the relationship between the dose of I-131 received and the risk of developing thyroid cancer. All of our previous "estimates" of that risk are based on extrapolating what we know about external radiation, which is based on many assumptions and is a very crude method for making such an estimate. NCI attempted to obtain more precise and valid data about exposure to I-131 and thyroid cancer from the population in Utah that was downwind from the Nevada Test Site, but these studies were inconclusive. However, children exposed to radiation from the Chornobyl accident may have received hundreds of times the dose received by children in the U.S. As I noted earlier in my statement, the exposures resulting from the Chornobyl accident, unfortunate as they were, now provide us with the opportunity to attempt to correlate exposures to and thyroid doses from I-131 with the onset of thyroid cancer and other health outcomes. We want to understand the dose relationship so that we can extrapolate back to a range of doses, specifically those in the U.S.

I have been asked many times to explain the difference between the risk estimate that was prepared last year when we released the I-131 report and the risk assessment we are trying to obtain from the Chornobyl study. Essentially, the difference is that the estimate prepared last year was not based on actual exposure of individuals to Iodine 131; it was rather an approximation of the number of cancers one might expect based on *what is known and published* about the relationship between exposure to radiation and the effect or outcome (thyroid cancer). This type of risk estimate can be prepared at any time using data available and already published in the scientific literature from many sources. The most important thing to remember about a risk estimate is to pay attention to all of the qualifiers, or limitations, that accompany it. The less that is known about an exposure, the broader the estimate will be, and the more uncertain the ability to validate its accuracy.

We knew people were concerned about their risk of developing thyroid cancer as a result of the fallout from the Nevada Test Site. I asked NCI staff to review and evaluate all available data on thyroid cancer, including incidence and mortality data, to see if there was any way to identify a change that might be related to I-131 exposure. These analyses did not find any such relationships that were statistically significant. NCI scientists were able, however, to obtain risk estimates for I-131 indirectly, based on the known relationships between thyroid cancer risk and exposure to radiation from external sources. To do this, they had to make reasonable assumptions about the relative effectiveness of radiation from these two types of radiation. This method resulted in a very broad estimate that ranged from 11,300 to 212,000 excess cases of thyroid cancer that *might* have been caused by exposure to I-131, but without a risk coefficient, the cause and effect relationship was based on assumptions. In their report, the IOM stated that, based on their own epidemiologic analyses, the excess of cancer cases is probably in the lower part of the range estimated by NCI. If the Chornobyl studies are successful, a much better estimate, with less uncertainty, will be possible because we will have direct evidence about thyroid cancer risk in persons exposed to I-131 that we can combine with the estimated doses from the Nevada Test Site.

How did NCI get involved in the Chornobyl study? As I mentioned in the beginning of my testimony, the Department of Energy (DOE) requested that one of our scientists, Dr. Bruce Wachholz, manage the scientific aspects of a large clinical radiation epidemiology study to be conducted in the former Soviet Union. This study grew out of an international agreement between Soviet President Gorbachev and President Reagan that called for bi-national cooperation in undertaking research to better understand the health consequences of radiation exposure resulting from the Chornobyl release. Dr. Wachholz's background in radiation biology, his experience with radiation dosimetry, and his familiarity with similar multi-disciplinary studies made him an obvious choice to lead this project on the U.S. side. Drawing from a pool of consultants who had previously served as advisors on other radiation studies, Dr. Wachholz assembled a prestigious working group to assist in the development and management of this activity. As a result of collaboration between U.S. and Belarus and Ukraine scientists and discussions with international organizations, the study was framed, the protocol was designed, and an assessment of available resources in the host countries (Ukraine and Belarus) was pursued. It is important to remember that this is a study of exposed individuals in Belarus and

Ukraine, being carried out by scientists and physicians in those countries, with advice and assistance from U.S. collaborators.

These studies are large, complex, and long term. We estimate that they may continue for 10-15 years. A timetable with target completion dates was developed as part of the protocols, and in addition a management plan was developed to assist us in guiding the overall project. The primary objective of the study is to carry out valid and credible assessments of the early and late morphologic and functional changes in the thyroid glands of persons exposed to radiation from radioactive materials released as a consequence of the Chornobyl Nuclear Power Plant accident. The emphasis is on obtaining data that allow us to develop a risk coefficient for thyroid cancer as it relates to dose, sex, and age in 1986 and on comparing the relative effectiveness of I-131 with that of x-ray and gamma irradiation in inducing thyroid cancer and other thyroid conditions.

From early 1991 through early 1994 (Belarus) and early 1995 (Ukraine), a U.S. working group, several members of which had previous experience with these types of studies, collaborated with working groups in Belarus and Ukraine, respectively, to develop the research protocols. Specific tasks were clearly spelled out, and approximate time lines were included. At the same time, government officials in Belarus and Ukraine were informed about the role of and need for an IRB and, following a period of training and education, established IRBs in their respective countries. During this period, another challenge facing the working groups was the need to interpret and translate all documents between Russian or Ukranian and English. The protocols were negotiated and approved by the international working groups and subsequently approved by IRBs in each country and by the NIH Office of Protection of Research Risks (OPRR). The Belarus protocol was signed and implemented in May 1994; the Ukraine protocol followed a year later, and was signed in May 1995. The delays in Ukraine arose due to a number of problems, including initial difficulties at the Ministerial level, including a hesitation to identify specific officials or agencies that would be responsible for the study. Once these difficulties were resolved, the degree of cooperation began to improve. However, we found that at times limited progress was made between NCI's visits, although these visits were pivotal in stimulating further activity. In 1997, the first study participants were screened at clinics set up for this purpose in Minsk and Kiev, and in mobile facilities. From 1994 through 1996, and following the signing of the protocols, work was carried out on the development of the operational infrastructure as spelled out in the protocols. This included such efforts as the development of operating manuals; exploring and developing methods to identify and locate the cohorts in each country; establishing data coordinating centers, data management, and creating data flow sheets; obtaining tax exemptions on equipment and supplies; and developing appropriate financial transfer arrangements; and putting in place a program of quality assurance;. Completion of these tasks was further complicated by the need to integrate various organizational entities and operating units into a cohesive project in order to undertake a study of this complexity with its need for rigor and absence of bias. Again, there was a need to translate additional critical documents between Russian or Ukranian and English and, very importantly, also adjust to several changes in Ministers in both countries. It is also fair to mention that, especially in the earlier years of the project, efforts were expended to overcome both the legacies of the Cold War as well as the significant scientific and cultural disparities.

My first meeting with DOE arose because of concerns they had about the progress and management of the study. I met with Dr. Paul Seligman, Deputy Assistant Secretary for Environment, Safety and Health, DOE in July 1996, and we agreed on a plan of action, including the establishment of a research support contract to develop and provide scientific and technical assistance in the project. In September 1997, NCI awarded such a contract to Columbia University following a full and open competition. The NCI official who serves as the Project Officer for this contract is Dr. Ihor Masnyk, who in recent years also has been the U.S. Associate Project Director.

Due to the considerable and complex pre-study activities that had to take place, it may appear that the Chornobyl studies have been slow to get underway. However, there were innumerable scientific, political, economic, and practical considerations and obstacles that were faced. These included changes in key government personnel (Ministers of Health) in Belarus and Ukraine, senior staff changes in Belarus, new laws and restrictions (such as import duties on technical equipment and financial transaction obstacles), changes in the physical location of key components, complex and changing organizational and interpersonal dynamics, delays in delivery of equipment and supplies due to the establishment of new foreign government oversight agencies, and many others.

Despite these delays, the study is moving forward. The cohorts have been established, study participants have been selected, methods for location of individuals are being evaluated, and feedback from individuals who have been invited to be screened is being gathered for evaluation. As of August 1998, in Belarus 2,869 patients have been screened, which is very close to the first year target of 3,000 screenings. In Ukraine, where screenings began three months ago, 529 study participants have been screened. Much of the credit for this progress is due to the ongoing activities of the working groups of consultants, whose members have provided regular and continuing guidance on these studies and have assisted in surmounting significant operational obstacles facing project execution. This U.S. assistance was provided by NCI staff and consultants (members of the working groups) through frequent trips to the study sites and regular monitoring of progress.

One of the specific milestones that is included in the protocols, and one that we have been asked to address, is the appointment of Bi-National Advisory or Oversight Committees. Such committees are required in each of the protocols, and based on the assumption that the studies would progress much more quickly, members were scheduled to be appointed during the first six months following the final approval (signing) of the protocols. Members are appointed by each national participant (five each from the U.S. and either Ukraine or Belarus), representing specific areas of expertise (endocrinology, radiation biology, radiation dosimetry, radiation epidemiology, and clinical sciences/pathology). The responsibilities of these oversight groups include those normally found in such studies done in the U.S., including recommending modifications of the protocols to the national authorities; approval of protocol modifications that have been agreed upon; review and approval of budgets prior to presentation to the national authorities; scientific and administrative oversight, including on-site visits and written scientific critiques; and developing a publication policy. All of these functions relate to the main activity of the studies, i.e. screening of participants. In addition, the Bi-National Advisory/Oversight Committees were given the responsibility to ratify the appointment of the Project Director in the study country. The process of identifying and appointing members for these committees has been quite slow, but all of the members of these committees have now been identified and we hope to schedule the first meetings in the near future. Has the absence of these committees had a negative impact on the conduct of the studies? We believe the answer, up to this point, is no; however with the accrual of study subjects, we have reached a point where the advice of the committees becomes important. Again, I must point out that these studies are cooperative, with NCI providing assistance but with the ultimate responsibility and authority resting with the Project Directors in the study countries. We believe that the study teams in Belarus and Ukraine match our own commitment to see the studies through to completion.

Interagency Coordination

There is a wealth of expertise and experience among Executive Branch agencies from which we can learn. Among the steps I have taken since becoming NCI Director have been efforts to improve communications with other federal agencies, especially with our collaborators. As I mentioned earlier, in July 1996 I and several other NCI staff met with our colleagues from the Department of Energy to reach an agreement on the future management of the Chornobyl studies. This was an important meeting as it addressed many of the issues under consideration today, and it was intended to provide a template for future open, honest discussions about our progress on these very important studies. Last September, I met with my counterpart at the National Center for Environmental Health at CDC, Richard Jackson. We discussed the many areas in radiation research where we could learn from each other, and we signed a joint memorandum committing our agencies to work more closely together, to identify new opportunities to collaborate on research initiatives, and to provide a forum for our staff to regularly exchange information on our progress. I am extremely pleased with the success of our renewed commitment, and I am confident that this will quickly translate into better, faster dissemination of important health information to the public.

Summary

An organization must be flexible to respond to changing needs and correct problems as they are encountered or identified. Last year, following the release of the I-131 report, I put in place several mechanisms to correct weaknesses I had identified in the process of trying to understand why this report took so long to complete. First, I assigned to the Deputy Director, NCI, the responsibility for monitoring and oversight of all radiation research conducted or supported by NCI. This placed the central coordination and monitoring function directly in my office where I could be immediately informed of any delays in or impediments to this area of research. Second, I directed that a comprehensive tracking system be developed to ensure that Congressional mandates such as this one would be monitored regularly and status updates provided periodically for better oversight and monitoring. This system has been developed and will be fully operational this fall. Third, over the past two years I have had ongoing conversations with key DOE staff, and with the Minister of Health in Ukraine, and have received only positive feedback about the conduct and progress of these studies. There is ample evidence to show considerable activity on these studies, including frequent trips overseas, frequent communications with project directors in Belarus and Ukraine, meetings with the contractor, and increased ability to successfully deliver needed equipment and supplies overseas to the appropriate recipients. My staff meet regularly with DOE staff to discuss progress on this study and have been informed that progress is satisfactory. We presented an update of the Chornobyl study to the National Cancer Advisory Board last week, and we are planning a presentation to the ACERER in November.

With all of these mechanisms in place, was there more we could have done or should have done in monitoring the Chornobyl study? A more detailed reporting of protocol benchmarks versus actual progress may have brought greater visibility to the delays associated with this study. However, because of the nature of the delays, it remains unclear to me whether this reporting in itself would have expedited progress. It is the complexity of conducting an international study in an unstable climate that has impacted progress. Time lines, milestones, and targets are all in place and significant progress has been made. I will readily admit that the study milestones may have been overly optimistic, especially knowing today what we do about the political, economic, and regulatory difficulties we have encountered. For those who focus on meeting milestones, this perhaps is viewed as a fundamental flaw. However, I believe that the optimism was based on our experiences here in the U.S. and the understanding that in clinical studies there are many contingencies that cannot be anticipated. Finally, I have asked the question myself: would functioning Bi-National Advisory Committees have made a difference in progress on these studies? After discussing this question with many of my own advisors, I have concluded that the guidance and advice provided by the working groups were sufficient to identify problems, issues and solutions as quickly as possible. This advice came from multiple sources, including our consultants on the project and more recently the staff on the Columbia contract. Many of these consultants have been affiliated with the project in varying capacities over the years and bring very different perspectives and valuable advice. The formal Bi-National Advisory Committees were not intended to function in such an operational mode, and their most valuable role relates to issues that are beginning to confront us now: issues of cohort identification; statistical strength; and our ability to complete the study as was originally conceived. I look forward to having these committees in place in the very near future so that they can begin their work.

I remain committed to ensuring that as long as NCI has responsibilities for these studies, they will be done well, in as timely a fashion as possible, and the results will be disseminated widely to the public and the scientific community. NCI clearly has the expertise needed to carry this out, and the responsibility to ensure that it is done well rests both with the scientific staff who manage the day to day issues and also with NCI management, where proper oversight must be maintained. I hope this testimony has clarified some of the issues of concern to the Subcommittee, and I will be pleased to answer any questions you may have.

STATEMENT OF WILLIAM F. RAUB, PH.D.

DEPUTY ASSISTANT SECRETARY FOR SCIENCE POLICY
OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

17 SEPTEMBER 1998

Madame Chairman, Senator Glenn, other members of the Subcommittee: I am William Raub, Science Advisor to the Secretary of Health and Human Services. I am pleased to be here today to discuss the perspective of the Department of Health and Human Services on the conduct of two studies designed to examine the effects of exposure to Iodine-131 following nuclear testing or accidents. My colleagues and I appreciate the time and attention the Subcommittee staff has devoted to its review of these studies. We share your desire that our research be conducted both rigorously and efficiently and that outcomes be used to promote national policies that are protective of the public health.

The studies selected for review by the Subcommittee involve attempts to understand the effects of two major cases of radiation exposure: one, the program of nuclear bomb atmospheric tests conducted at the Nevada Test Site by the former Atomic Energy Commission; and two, the Chernobyl nuclear power plant accident. In both cases, people were exposed to Iodine-131 and other radionuclides for reasons beyond their control and, for many individuals, without their knowledge. The Department recognizes as understandable and legitimate the frequently expressed concern that the exposed populations in both cases may be at higher risk of diseases of the thyroid, particularly cancer.

The National Cancer Institute is the appropriate organization to direct research toward resolving this concern. It has the requisite expertise and experience. In particular, its staff includes leading international authorities on radiation epidemiology and radiation dosimetry.

You have raised important questions about our response to Public Law 97-414, which directed the Department to "(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131; (2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; and (3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests ....". NCI clearly took too long to complete the study. We have learned important lessons about use of resources and the setting of priorities as a result of our experience with the Iodine-131 study. The Department will review its procedures for monitoring such major studies, and where necessary, will institute reforms to ensure that we do not repeat the experience of the Iodine-131 study.

As you know, the Institute of Medicine (IOM) reviewed the NCI study and recently issued its own report. IOM assessed the soundness of NCI's analyses and assumptions and its estimates of risk of thyroid disease from Iodine-131 fallout. IOM also analyzed the issues associated with population-based screening for thyroid cancer and the challenges associated with providing clear and useful information about the risks of both radiation and screening to those who have been exposed. We are currently studying IOM's report so that the Department can be responsive to its findings.

I call your attention to the fact that IOM did not recommend population-based screening for people exposed to radiation fallout. Testimony earlier today from the Agency for Toxic Substances and Disease Registry (ATSDR), however, indicates that it recommends medical monitoring for people exposed to radiation from the Hanford nuclear reactor. In his testimony, Dr. Johnson of ATSDR compared his agency's recommendation with the IOM findings. He correctly noted that ATSDR and the NCI studies differ considerably with regard to circumstances, methodology, outcomes, and requirements.

On their face, the ATSDR and IOM conclusions do not appear to be in conflict. However, the Department will review policies and practices at the Centers for Disease Control and Prevention (CDC), ATSDR, and NCI to identify significant differences, if any, in their respective approaches to dose reconstruction and determinations regarding the need for and feasibility of population-based screening or medical monitoring. If we find any differences that we believe jeopardize the Department's ability to be protective of the public health, we will initiate corrective action.

The ongoing NCI study of the Chernobyl disaster is a unique opportunity to examine the effects of radiation on people. We have confidence that the Institute is on course toward identifying proper cohorts, estimating exposure, and assessing risks of disease.

The Department is aware of the difficulties of conducting such research in countries that had been part of the former Soviet Union. The science of epidemiology is not as uniformly well developed there as here; in many cases, resources and experience lag far behind those available in the United States; and managing a major international study in an area of the world that is experiencing significant political and economic instability is a difficult undertaking. As a consequence, I do not think we should judge the progress of the Chernobyl study using the same standards that we would apply to a study conducted in the United States.

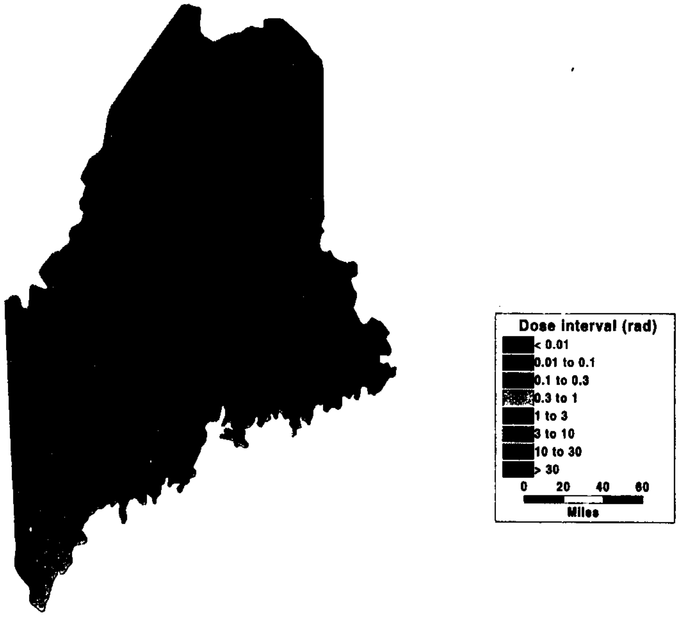
Nevertheless, the Subcommittee has raised several important management issues related to the Chernobyl research. Because this research is so important and, we hope, the only opportunity we ever have to study such exposure to human beings, the Department wants to be certain that the Chernobyl work is done as effectively and efficiently as possible. We recognize the concerns of the Subcommittee, and we take them seriously. I will work with NCI staff to arrange for an independent review of the Chernobyl project to identify any problems associated with the way the work is planned, organized, conducted, and overseen.

Our plan to seek an independent review does not mean we lack confidence in NCI. To the contrary, we believe NCI is the right place to conduct this research; and we are intend upon doing everything reasonable toward ensuring that the project remains appropriately oriented and proceeds as expeditiously as circumstances allow. We will await the outcome of the independent review with an open mind.

Thank you for the opportunity to testify today.

Estimates of I-131 thyroid doses (rad) for persons born on January 1, 1952 (Average diet; average milk consumption)

State: MAINE

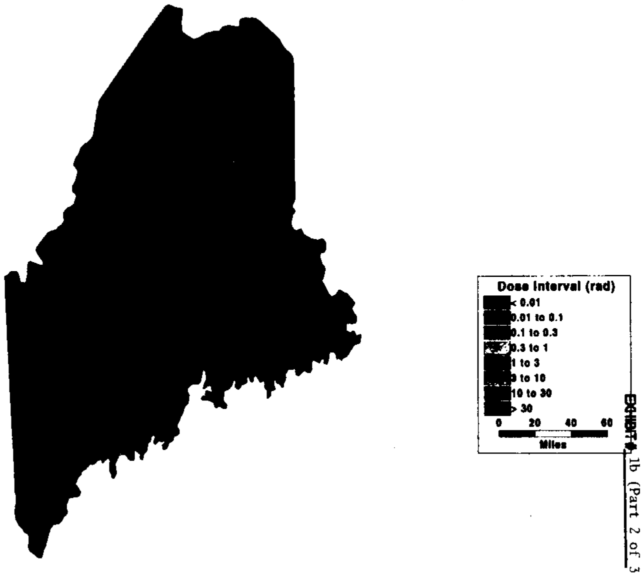


Senate Permanent Subcommittee
on Investigations

EXHIBIT # 1b (Part 1 of 3)

Estimates of I-131 thyroid doses (rad) for persons born on January 1, 1952 (Average diet; high milk consumption)

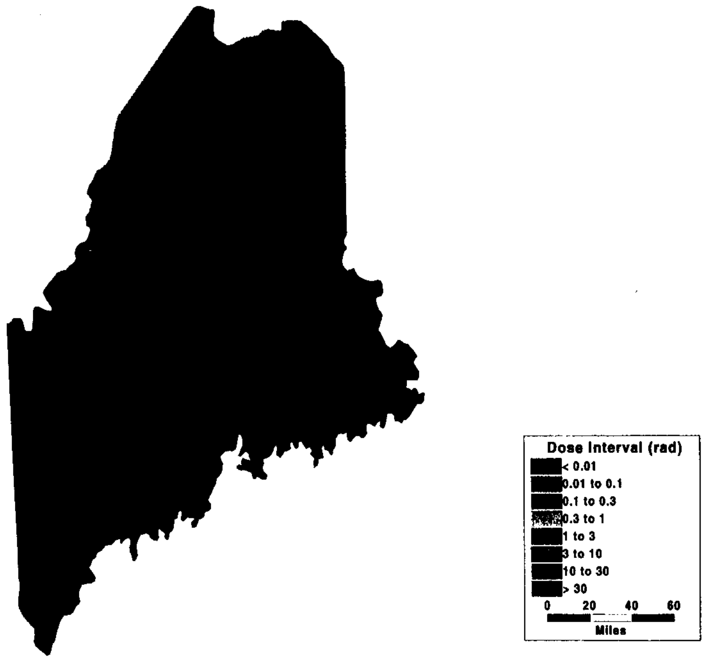
State: MAINE



Senate Permanent Subcommittee
on Investigations
EXHIBIT # 1b (Part 2 of 3)

Estimates of I-131 thyroid doses (rad) for persons born on January 1, 1952 (Average diet; milk from backyard cow)

State: MAINE



Senate Permanent Subcommittee
on Investigations

EXHIBIT # 1b (Part 3 of 3)

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 2

TIMELINE OF EVENTS
NATIONAL CANCER INSTITUTE'S I-131 REPORT

December 1950:	Nevada Test Site (NTS) established by order of President Truman.
1951- 1958:	Atmospheric testing of Nuclear Bombs begins at the Nevada Test Site. Approximately 97 atmospheric tests were conducted between 1951-1958.
August 1963:	Limited Nuclear Test Ban Treaty signed, ending atomospheric testing.
January 1983:	P.L. 97-414 enacted. Section 7(a) directed HHS to conduct a study of the exposure, dose, and risk to the American people of thyroid cancer from exposure to Iodine 131 as a result of above ground nuclear testing in Nevada. Responsibility for implementing the study delegated from HHS to the National Cancer Institute.
April 1987:	Court finds plaintiffs suffered damage from Nevada testing, but holds U.S. Government not liable for damages due to its "discretionary function" immunity.
1984-1990:	NCI develops substantive scientific data on dose and exposures. Preliminary results indicate that much higher doses of radioactive iodine were received nationwide than previously known. The data indicated that doses on the east coast were comparable to those in Nevada and Utah.
October 1990:	In response to court actions, Congress enacts the Senate's Radiation Exposure Compensation Act, providing that in certain specified circumstances individuals exposed to testing fallout in states near the site, Nevada, Utah and Arizona only, could receive compensation.
1992:	NCI writes a draft report to Congress stating that the dose and exposure aspects of the study are complete and will be forwarded to Congress during 1992.
1990-1993:	Final draft of NCI report with maps and data for individual counties completed, but not published.
1992 -1995:	Annual Reports of the NCI Division of Cancer Etiology state each year that "Activities [pertaining to dose and exposure] have been completed and a final report has been prepared."
September 1993:	Advisory Committee for the Fallout Study disbanded.
1994:	Completed draft report given to NCI Branch Chief overseeing study.

May 1996:	A federal advisory committee, The Advisory Committee on Energy-Related Epidemiologic Research (ACERER) requests NCI to provide information regarding the study. After three separate inquiries, response finally received in March 1997, stating the technical component is complete and NCI plans to publish the report during fiscal year1997.
April 1997:	Senator Daschle's office makes inquires about progress of the study. NCI Director Richard Klausner learns of delays in issuing report, and orders a full-scale effort to finalize and publish report.
October 1997:	NCI issues fallout study fourteen years after it was started. The published study addressed only 2 of the 3 issues mandated by Congress, failing to assess the risk to public health from the fallout.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 3

MEMORANDUM

TO: **PERMANENT SUBCOMMITTEE ON INVESTIGATIONS**

FROM: **ROBERT ROACH, Senior Counsel**
BETH STEIN, Counsel
WILLIAM MCDANIEL, Investigator
Permanent Subcommittee on Investigations, Minority Staff

RE: **PSI HEARING ON THE NATIONAL CANCER INSTITUTE'S MANAGEMENT OF RADIATION HEALTH EFFECTS RESEARCH**

OCTOBER 1998

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SUMMARY

From 1951 to 1962, the United States government conducted 100 atmospheric (above ground) nuclear bomb tests[1] at the Nevada Test Site established by President Truman in 1950.[2] The vast majority of atmospheric tests (97) were conducted between 1951 and 1958.[3] As a result of the tests, radioactive iodine, referred to as "Iodine 131," (I-131) was released into the atmosphere. Once in the atmosphere, the I-131 was transported by prevailing winds until it was deposited on the ground by precipitation.

I-131 is a radioactive isotope with a short half life (8 days). When ingested by humans, I-131 can concentrate in the thyroid gland, which uses iodine to produce hormones. It is an established fact that some I-131 made its way into the human diet during the 1950s when cows and goats ingested I-131 that had been deposited on soil and in plants and then produced milk for human consumption. Thyroid doses from I-131 intake is most dependent upon the size of the thyroid gland and the amount of milk consumed. Therefore, children, who have small thyroids and tend to drink a lot of milk, are most susceptible to receiving high doses of I-131. The most troubling form of human consumption of I-131 occurred when children in the 1950s drank unpasteurized milk, which had higher concentrations of I-131 than pasteurized milk. This consumption was particularly troubling because children drank a significant amount of unpasteurized milk at that time.

What was not known at the time, however, was the extent or full effect of the radiation exposure imposed on American children or the American population at large. The Subcommittee's hearing will explore how the federal government conducted an important research project to answer that question.

In 1983, Congress mandated the Department of Health and Human Services ("HHS") to conduct a study to determine exposures and doses resulting from the release of I-131 from U.S. atmospheric weapons testing at the Nevada Test site, and assess the risk of thyroid cancer associated with doses of I-131. Fourteen years later, on October 1, 1997, HHS's National Cancer Institute (NCI) issued its study, entitled "Estimated Exposures and Thyroid Doses Received By The American People From Iodine 131 in Fallout Following Nevada Atmospheric Nuclear Bomb Tests." Although the study was essentially completed in 1992, it was not released until 1997, and even then, it failed to address one of the crucial Congressional mandates: the public's risk of thyroid cancer associated with doses of I-131.

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[1] National Cancer Institute report, "Estimated Exposures and Thyroid Doses Received by the American People from Iodine-131 in Fallout Following Nevada Atmospheric Nuclear Bomb Tests, October 1997" (hereafter referred to as "the I-131 study", or "the NCI study"), pp. 2.2, 2.8 and 2.10.

[2] Fradkin, Philip, L., Fallout - An American Nuclear Tragedy. Tucson: the University of Arizona Press, 1989, pp. 92-93.

[3] The I-131 study, p. 2.2.

The report contains data that raise serious questions about the delay in its publication:

- High levels of fallout were not limited to those areas near the test site in Nevada. In a number of areas of the U.S., including the northern plains, the Midwest and Northeast, individuals received doses of I-131 to their thyroid that were comparable to, and in some cases exceeded, the doses received by citizens living near the test site itself.[4]

- Americans across the nation received doses of radiation at levels that were much higher than previously believed.[5] It is estimated that 3.5 million children may have received an average cumulative dose of 10.3 rads of Iodine 131 [6] and that some children may have received cumulative doses as high as 100 rads.[7]

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[4] The I-131 study, pp. ES 2 and TS. 10. See, also, the maps of estimated thyroid doses in Chapter 8, "Estimated Thyroid Doses Resulting from Atmospheric Bomb Tests Conducted at the Nevada Test Site."

Table 1.1, p. 29, *Committee on Thyroid Screening Related to I-131 Exposure,* Board on Health Care Services, Institute of Medicine and *Committee on Exposure of the American People to I-131 from the Nevada Atomic Bomb Tests,* Board on Radiation Effects Research , Commission on Life Sciences, National Academy of Sciences, "Exposure of the American People to Iodine-131From Nevada Nuclear-Bomb Tests: Review of the National Cancer Institute Report and Public Health Implications," National Academy Press, 1998. Hereafter referred to as "the NAS report". Table 1.1 is included with this report as ATTACHMENT 1.

[5] In 1959, the AEC estimated that if an adult consumed a quart of milk per day, the annual dose of I-131 to the thyroid would be approximately 37 millirads. (.037 rads). The dose to a child was estimated to be 10 to 15 times higher (.37 to .555 rads). "Discussion of Dosage from Short-Lived Isotopes in Worldwide Fallout, Submitted by the AEC" in "Hearings before the Special Subcommittee on Radiation of the Joint Committee on Atomic Energy, Congress of the United States, Eighty-Sixth Congress, First Session, on Fallout from Nuclear Weapons Tests," May 5,6,7 and 8, 1959, Volume 2, pp.1806-1807. Thus, over the 10 year testing period, it would be expected that a child would receive a cumulative dose of 3.7 to 5.5 rads.

[6] Data on the numbers of individuals in various age groups estimated to have received certain average cumulative doses are presented in Memos to Dr. Richard Klausner, Director, National Cancer Institute, from Dr. Charles Land, Ph.D., Health Statistician, DCEG/EBP/REB, "Calculation of lifetime thyroid cancer risk for an average thyroid dose of 0.02 Gy from L-131 in fallout (corrected).", December 18, 1997; "Uncertainty of estimated thyroid cancer risk related to L-131 fallout from the Nevada Test Site: Correction of my memo of September 23, 1997, and some related developments.", December 19, 1997(attachment #1 to first memo); and "Calculation of the Estimated Lifetime Risk of Radiation-Related Thyroid Cancer in the U.S. Population from NTS Fallout. (Presented at the NAS/IOM advisory committee meting, 12/18/97" (attachment #2 to first memo). Hereafter referred to as "Land memos." ATTACHMENT 2. The average thyroid doses for various age groups used in the Land analysis were developed by Dr. Andre Bouville, primary author of the I-131 report, based on data generated in the study. However, the average doses for various age groups do not appear anywhere in the report.

[7] Statement of Dr. Richard Klausner, Hearing before the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Committee on Appropriations, United States Senate, "Radioactive Fallout From Nuclear Testing At Nevada Test Site, 1950-60," 105th Congress, 1st Session, S. Hrg. 105-180, October

- NCI has since estimated that 11,000 to 212,000 people may develop thyroid cancer from the weapons test fallout.[8]

The Subcommittee staff reviewed NCI's management of the study. That review has identified important issues related to governmental openness and effective management of radiation health effects research.

- The publication of the study was delayed for at least 4 years and perhaps longer. NCI failed to meaningfully assess and adequately inform the American people of the impacts of the fallout from the weapons tests.

- The NCI study was plagued by mismanagement, lack of internal oversight and a lack of public participation and openness.

- The NCI is currently having similar problems managing the U.S. government's participation in critical studies of the health impacts of the Chernobyl accident. Those studies could provide more information on the risk posed by radioactive iodine fallout.

- HHS does not have any Department-wide policies or guidelines governing the conduct of sensitive studies related to radiation health effects research, even though its agencies now perform many of those studies for the government.

The major objectives of the hearing are:

- To better inform the American public of how they were affected by the fallout from the nuclear weapons tests at the Nevada Test Site and what public health issues are raised by those impacts.

- To review the NCI's management of the I-131 study and related studies on the health impacts of the Chernobyl accident.

- To seek a commitment from HHS to establish agency-wide guidelines for radiation research that will open studies to public involvement and that are directed toward public health goals.

1, 1997, pp. 8 and 12.

[8] Land memos. ATTACHMENT 2.

BACKGROUND

In the area of nuclear weapons testing, the federal government has a long history of not providing important health information to the American public in a timely fashion. In the 1950's and early 1960's, a very large number of Americans, especially children and infants, were put at risk by radioactive fallout from atmospheric nuclear weapons tests conducted by the federal government. There is substantial evidence that throughout the testing period the federal government strongly suspected, or knew, that the tests would yield radioactive fallout at levels that could pose a health threat to American citizens. Yet, the public was not alerted in advance of the tests or warned to take precautionary measures. For many years after the tests the government did not study or reveal the possible impacts of the tests on the American public.

Fall Out From Testing in the 1940s

As early as 1945, the government was aware that fallout from atmospheric nuclear tests could travel far from the site of a detonation. When the first nuclear bomb was detonated in New Mexico in July 1945, fallout was quickly detected 200 miles from the detonation site.[9] This discovery resulted in a memo from the project's chief of radiological safety recommending that future tests be conducted at least 150 miles from civilian populations.[10] Shortly thereafter, fallout from the 1945 test was detected in Indiana, over 1,000 miles from the test site. This fallout was discovered when the Eastman Kodak Company received complaints of "fogged" x-ray film. The film was packed in material made from corn husks at a plant in Indiana. An investigation determined that the film was fogged because the corn husks contained radioactive material derived from an atomic explosion.[11]

Establishment of a New Test Site In Nevada

At this time, the federal government was seeking a new location to conduct additional nuclear testing. As part of those deliberations, a U.S. Air Force meteorologist recommended to the government that the new site be located on the east coast. The proposed testing, like the testing in 1945, would release radioactive material into the atmosphere which would then travel hundreds, even thousands, of miles depending on prevailing winds. The meteorologist stated that the exposure to the population would be minimized by an east coast site "because the United States is predominantly under the influence of westerly winds."[12] Despite this recommendation, the government established its new test site in Nevada on December 18, 1950.[13] Although in a sparsely populated area, the Nevada site was proximate to U.S. weapons laboratories and therefore beneficial in accelerating the pace of the weapons development program.[14]

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[9] Col. Stafford L. Warren, Chief of Medical Section, Manhattan District, July 21, 1945, memorandum to Major General Groves, "Report on Test II at Trinity, 16 July 1945," pp. 2-3. ATTACHMENT 3. See also, Ortmeyer, Pat and Makhijani, Arjun, "Worse Than We Knew," The Bulletin of the Atomic Scientists, Nov.-Dec. 1997 issue, p. 47. ATTACHMENT 4.

[10] Ibid.

[11] Ortmeyer & Makhijani, "Worse Than We Knew," p. 47. ATTACHMENT 4. See also, U.S. Atomic Energy Commission January 17, 1952, report by the Director of Military Application, Summary of Relations Between The AEC And The Photographic Industry Regarding Radioactive Contamination From Atomic Weapon Tests, From January Through December 1951. ATTACHMENT 5. See also, Testimony of Senator Tom Harkin, Hearing before the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Committee on Appropriations, United States Senate, "Radioactive Fallout From Nuclear Testing At Nevada Test Site, 1950-60," 105th Congress, 1st Session, S. Hrg. 105-180, October 1, 1997, p. 3.

Government Provides Selective Warnings To Industry Leaders

During the atmospheric test explosions from 1951 to 1958, the government was alerted to the fact that weapons testing fallout was affecting certain products throughout the country and decided to provide advance warnings of the tests to leaders in the photographic film industry. After the first test at the Nevada Test Site ("NTS") in January 1951, Kodak again experienced problems with fallout - - this time at its company headquarters in Rochester, New York. Apparently, a heavy snowstorm deposited large amounts of radiation causing company geiger counters to display readings 25 times above normal. Complaints and threats of a Kodak law suit against the Atomic Energy Commission ("AEC") resulted in the government agreeing to give the company advance warning of future tests, including expected distribution of radioactive material in order to anticipate local contamination. Not only was Kodak warned, but the photographic film industry received warnings about fallout. The AEC provided the industry with maps and forecasts of potential contamination and fallout distributions, enabling the companies take necessary precautions.[15]

Unfortunately, although the AEC decided to notify the photographic industry, it failed to warn dairy farmers and other citizens of the United States of their exposure to fallout, thereby precluding the American population, especially those families with children who drank unpasteurized milk, from taking precautionary measures to safeguard their health.

In the mid-1950s, agricultural interests also complained about the effect of radiation on sheep located near the Nevada Test Site. Following nuclear bomb tests in 1953, approximately

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[12] Colonel B.G. Holzman, USAF Staff Meteorologist, April 21, 1948 memorandum to Admiral Parsons, "Subject: Site for Atom Bomb Experiments." ATTACHMENT 6.

[13] Fradkin, p. 93.

[14] Dean, Gordon E., "Location of Proving Ground for Atomic Weapons - Selection of a Continental Atomic Test Site," Report by the Director of Military Application, December 13, 1950, p. 5. ATTACHMENT 7. See also Ortmeyer and Makhijani, "Worse Than We Knew," p. 46. ATTACHMENT 4.

[15] U.S. Atomic Energy Commission, Twenty-first Semiannual Report of the Atomic Energy Commission, January 1957, pp. 210-211. ATTACHMENT 8.

12% of the entire ewe population and 25% of the entire lamb population in the area of the Nevada Test Site died.[16] Upon investigation, veterinarians and the AEC found signs of radiation exposure, leading one investigator to reportedly comment, "these sheep are hotter than a two dollar pistol."[17] However, the final report published by the AEC in 1954 concluded that the losses and damages suffered by the sheep were not caused by radiation. The representations made by the government in the case were later found to be fraudulent by a federal district court in 1982.[18]

Government Knowledge of Health Effects on Humans

In addition to evidence that established that weapons testing released radioactive material that often traveled a great distance before being deposited on the ground and that the deposits had affected film and animals, the government also had evidence as early as1953 that these deposits affected the production of milk. Studies at the time warned that these deposits posed troubling health risks to children because of their milk consumption and their small thyroids, which resulted in high concentrations of I-131 in their thyroids.[19]

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[16] House Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, Committee Report, "The Forgotten Guinea Pigs - A Report on Health Effects of Low-Level Radiation Sustained as a Result of the Nuclear Weapons Testing Program Conducted by the United States Government," 96th Congress, 2nd Session, Committee Print 96-IFC 53, August 1980, p.3.

[17] Testimony of Jack Pace before the House Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, Committee Report, "The Forgotten Guinea Pigs - A Report on Health Effects of Low-Level Radiation Sustained as a Result of the Nuclear Weapons Testing Program Conducted by the United States Government," 96th Congress, 2nd Session, Committee Print 96-IFC 53, August 1980, p.5.

[18] In a 1955 legal case, sheep owners brought suit against the federal government, alleging that the nuclear tests damaged their herds. At the trial, the court noted that, "the Government was negligent in monitoring the tests in view of the presence of sheep herds in areas likely to be affected...there were no advance warnings given or other precautions taken to safeguard the herders or their sheep...and the Atomic Energy Commission did not attempt to ascertain the location of the sheep with or without reference to any prospective pattern of fallout dependent upon winds." However, based on testimony presented, the court found that the amount of radiation the sheep were exposed to did not cause the damage, and found in favor of the government. After additional information was uncovered in the 1970s, a district court in 1982 found that the government had acted fraudulently in presenting evidence in the 1955 case. Bulloch v. United States, 145 F. Supp. 824 (D. Utah 1956), vacated, 95 F.R.D. 123 (D. Utah 1982), rev'd, 763 F.2d 1115 (10th Cir. 1985).

[19] Among the studies that alerted the government to the contamination of milk from nuclear testing fallout were: a 1953 study conducted by the Hanford Nuclear Reservation regarding milk from sheep that had been fed I-131 pellets. This study concluded that similar iodine levels in cow's milk suggested that I-131 would be found in dairy products, such as skim milk, cottage cheese, and whey. Also in 1953, the Public Health Service obtained milk samples in St. George, Utah for analysis. However, the sample was taken from a carton of milk purchased at a store, rather than from a local dairy or farm. Most of the residents of that area during that time drank milk from backyard cows or neighboring farms. According to a Public Health Service Fallout Monitor, the testing procedure for milk samples was flawed because the milk was treated with perchloric acid to remove organic residue, and such oxidating techniques eliminated iodine. Ortmeyer & Makhijani, "Worse Than We Knew," pp. 48-49.

In fact, in 1954, an AEC report recommended that in order to reduce radioactive deposits, nuclear tests be concentrated in the late fall - - a season in which storms (and therefore precipitation) were traditionally least likely to occur. However the recommendation was mostly ignored.[20]

Another example of the government's knowledge of the danger of fallout from nuclear testing appeared in Stewart Udall's book, "The Myths of August." According to Mr. Udall, Dr. Norris Bradbury, director of the government's Los Alamos Laboratory, took specific actions to protect his family and grandchildren from the Nevada Test Site fallout, going so far as to provide safety tips to his family to avoid exposure and provide them with transportation out of the area at certain times.[21]

In 1979, plaintiffs sued the United States, alleging that the radioactive fallout from the Nevada Test Site had resulted in health injuries to "downwinders" (those individuals who were downwind from the Nevada Test Site). The district court held that the United States negligently "failed to adequately warn" off-site residents of known or foreseeable long-range biological consequences to adults and to children from exposure to fallout radiation from open air atomic testing; failed to measure adequately and concurrently with open air atomic testing the actual fallout near the test site on a person-specific basis; and failed to adequately warn communities during the testing of ways to prevent long-range biological consequences of exposure to fallout.[22] In 1987, the Tenth Circuit reversed this holding, finding that the AEC was protected from liability by the government's discretionary function exception.

ATTACHMENT 4. In 1962, Dr. Harold Knapp with the AEC Division of Biology and Medicine, Fallout Studies Branch, produced a report, "Iodine 131 In Fresh Milk And Human Thyroids Following A Single Deposition of Nuclear Test Fallout." The report indicated that after the 1953 NTS Harry shot, "The associated doses to an infant thyroid would be in the range of 120-440 rads..." Initially the AEC attempted to suppress the report, but eventually released it on June 1, 1963.

[20] Ortmeyer & Makhijani, "Worse Than We Knew," p. 49. ATTACHMENT 4.

[21] Udall wrote: "In 1962, members of Norris Bradbury's family were 'living under' fallout in a dangerous corridor of the downwind zone at Zion National Park, due east of St. George [Utah]. His son, a park ranger, his pregnant daughter-in-law, and his first grandson, age two, resided in a canyon near the park . Bradbury surely knew that small children - and especially embryonic children in utero - were exceptionally vulnerable to the impacts of low-level radiation. As a result, he made a special trip to Zion and took action to protect his grandchildren. He showered the parents with safety tips ('Keep them indoors on windy days...don't let them eat snow,' etc.) And provided airline tickets to his daughter-in-law so she and her son could visit relatives during the month-long 1962 tests. Norris Bradbury behaved as a concerned grandparent should have - but the acts he performed in secret to protect his family attest that the bomb testers knew the downwinders faced dangers...." (Udall, Stewart L., *The Myths of August*, New Brunswick, New Jersey, Rutgers University Press,1998, pp. 248-249.)

[22] *Allen v. United States*, 588 F. Supp. 247 (D. Utah 1984), *rev'd* 816 F.2d 1417 (10th Cir. 1987)

The Government's Continued Failure To Provide The Public With Information

The government's failure to inform the public of the known health risks from the Nevada Test Site during the 1950s and 1960s was examined by the U.S. House of Representatives Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations in 1980. The Committee issued a report, "The Forgotten Guinea Pigs," summarizing the facts and findings of four Subcommittee hearings conducted from April 19 through August 1, 1979. Testimony received, and documentary evidence brought forth at the hearings revealed an alarming indifference on the part of government officials regarding the health of those individuals exposed to radiation from the nuclear tests. Indeed, their actions went beyond indifference as they failed to notify the public of precautionary measures to protect themselves, minimized estimated radiation doses, and concealed the true dangers of the exposures received.

Among the findings of the report are:

- As early as 1953, the government was aware of the potential health hazards posed to humans by the internalization of radionuclides absorbed through the food chain system.
- The government failed to take measurements of milk contamination by radioisotopes, upon which to establish safety standards for internal exposures, until 1957. Moreover, the government refused to alter the levels subsequently set for internal radiation exposure even after a 1963 scientific report concluded that the government's original assessment of the hazard was far too low.
- The government disregarded personal reports of radiation-related illnesses, which demonstrated potentially higher radiation levels than those actually measured by the government's monitors.
- The government publicly espoused the safeness of the atmospheric nuclear testing program and refrained from alerting the public to the known or potential health hazards associated with exposure to radioactive fallout.[23]

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[23] House Committee On Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations report - "The Forgotten Guinea Pigs - A Report On Health Effects of Low-Level Radiation Sustained As A Result of the Nuclear Weapons Testing Program Conducted by the United States Government," 96th Congress, 2nd Session, Committee Print 96-IFC 53, August 1980, pp.17-18.

Peter Libassi, former General Counsel for the Department of Health and Human Services, testified that "the press releases which were finally issued [by the AEC] did not contain the information and warnings and concerns and questions that were already emerging.... During the late 1950s and 1960s there was increasing evidence that these levels of radiation were not safe. Despite this growing evidence, there seemed to be a reluctance or unwillingness to share with the American people the fact that there were growing questions about the safety of low levels of radiation. There seemed to be an unwillingness to address those issues, to pursue the research, and to disclose the information to the public... The American people were not informed of the evidence that was gathered during the 1950s and 1960s on the health effects of radiation from these atmospheric nuclear tests." ("Health Effects of Low-Level Radiation," Joint Hearings before the House Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce and the Senate Subcommittee on Health and Scientific

Based on information derived from congressional hearings in the 1970s, the plaintiffs who had brought action in 1953 for damage to their sheep asked the court to reconsider its opinion about the radioactive damage done to the sheep in the Nevada Test Site area. The judge found by clear and convincing evidence that the government's denial of the health effects of the testing in the 1950s "amounted to a species of fraud on the court" done "to advance the perceived interests of the United States in the unimpeded testing of nuclear weapons and to prevent this program from being needlessly interfered with or embarrassed by judicial action."[24]

Finally, congressional testimony in 1997 reaffirmed the government's longstanding unwillingness to provide information about the public health risks associated with weapons testing. Dr. Joseph Lyon, a professor of family medicine at the University of Utah, was the principal investigator for a study in the 1980's examining the health impacts of atomic fallout on Utah citizens. Dr. Lyon compared the government's treatment of two studies: one on leukemia and another on thyroid cancer. Lyon testified that the results of the leukemia study, known by the government in 1964, found "about a threefold excess of cancers among children who were under age 19 living in these two southwestern counties." In contrast, Dr. Lyon testified that a poorly done thyroid study found no adverse health affects. Dr. Lyon testified that the leukemia study was "buried in the files of HHS after a high level meeting at the White House because of its impact" whereas the thyroid study was published, highlighted, and used to reassure the citizens of Utah.

Dr. Lyon concluded that:

> The principles [governing the government's treatment of radiation research] were as follows: suppress any data that suggests a positive association between exposure and subsequent cancer and mask your motives by stating that you do not want to unduly alarm the people who were exposed. Cite only studies that found no association to reassure people that their health concerns are groundless. And finally, do everything possible to make sure that no further scientific studies will be done that might contradict your position. When you can't suppress findings of adverse effects from NTS fallout, publicly label the results as inconclusive, knowing full well that the investigators cannot counter your 'spin.'[25]

Research of the Committee on Labor and Human Resources and the Committee on the Judiciary, 96th Congress, 1st Session, serial Nos. 96-41 and 96-42, April 19, 1979, pp. 99-100.)

[24] Bullock v. United States, 95 F.R.D. 123 (D. Utah 1982), rev'd, 763 F.2d 1115 (10th Cir. 1985).

[25] Testimony of Dr. Joseph Lynn Lyon, Hearing before the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Committee on Appropriations, United States Senate, "Radioactive Fallout From Nuclear Testing At Nevada Test Site, 1950-60," 105th Congress, 1st Session, S. Hrg. 105-180, October 1, 1997, pp. 17-23.

II. THE NCI I-131 STUDY

In 1983, in response to mounting public concern over possible health impacts of the testing program, Congress mandated that the Department of Health and Human Services (HHS) conduct a study to examine the extent of exposure, dosage, and risk to the American public due to I-131 fallout from above ground nuclear testing conducted at the Nevada Test site. Specifically, Section 7(a) of P.L. 97- 414, the Orphan Drug Act, directed the Secretary of HHS to:

> (1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;
>
> (2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; and
>
> (3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests.

HHS delegated the responsibility to NCI, where it was assigned to NCI's Low Level Radiation Effects Branch (REB). The project was headed by the Chief of the REB, Dr. Bruce Wachholz. NCI initially convened an ad hoc panel of experts to conduct the study. In addition, a number of technical consultants were hired to assist the REB and the panel.

The first meeting of the panel was held on September 6 and 7, 1983. In 1984, the Ad Hoc Committee was established as a formal Advisory Committee. The Chief of the REB served as chairman of the ad hoc panel and the subsequent Advisory Committee. The Advisory Committee created three task groups to develop assessments of: (1) the amount of radioactive iodine deposited around the country; (2) the amount of exposures suffered by citizens around the country; and (3) the risk to humans from I-131 exposures. To develop its estimates, the NCI used test data available to estimate the amount of radiation released into the atmosphere. The weather patterns at the time of testing were studied and, using data available from approximately 100 monitoring stations that were operated during the time of testing, an estimate was made of the amount of radioactive iodine that was deposited into the food chain around the country. The study also relied on data that showed that human exposure primarily resulted from fallout being deposited on pasture grass, concentrating in milk from cows and goats and being ingested by humans. Through this process the NCI estimated doses to citizens from the fallout.

On October 1, 1997, the NCI released a partially completed report - fourteen years after it was mandated by Congress. The report addressed two of the three issues included in congressional mandate: those related to I-131 exposures and thyroid doses. The report reveals that the fallout from the above ground nuclear weapons tests was more widespread, and the doses of radiation received by the public much higher, than previously acknowledged by the government.[26] The manner in which the preparation and release of the report were handled raises issues of governmental openness and effective management of radiation health effects research. For instance, why did it take 14 years to complete and release the study? Why didn't NCI address the issue of risk? Why was there no public involvement in the study? Why weren't critical results shared in a complete and timely fashion with Congress and other interested parties who had a vital need for the information? Why did NCI management virtually ignore the study and fail to monitor its progress? These questions are particularly important in light of the federal government's long history of withholding information from the public on these issues and in light of the data contained in the study. Analyses of those data raise the following issues:

- Millions of children across the nation, including those living on the east coast, received doses of radiation at levels that were much higher and posed greater health risks than previously believed. It is estimated that 3.5 million children received an average cumulative dose of 10. 3 rads of radioactive iodine (I-131). Another 14 million children received an average cumulative dose of 6.7 rads.[27]

- In some parts of the country the estimated doses to individuals from a single nuclear test series (i.e., a number of individual tests, generally lasting for a period of a few months or less) were high enough to exceed the annual dose limit for children (1.5 rads) recommended by the National Council on Radiation Protection and Measurements (NCRP).[28]

- NCI has estimated that 11,000 to 212,000 people may develop thyroid cancer from the weapons test fallout.[29] Although not addressed in the report because it was not part of the Congressional mandate, there is also a question whether an undefined number of individuals will suffer from other thyroid diseases, such as hypothyroidism, as a result of the doses that they received.[30]

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[26] See footnote 5.

[27] Land memos, ATTACHMENT 2.

[28] After the NCRP recommended the 1.5 rad annual limit for children in 1954, the government conducted a test series at the Nevada Test Site (which generally lasted a few months or less) that caused I-131 fallout so large in some areas of the country that the resulting estimated doses to children exceeded the recommended annual dose limit of 1.5 rads. See Figure 8.74 , "Estimates of I-131thyroid doses resulting from the test series Plumbbob (May-October 1957)," the I-131 Report, p. 8.42. The sub-annexes of the I-131 report, accessible through the NCI web site (http:www2.nci.nih.gov/fallout/html), enable individuals to calculate the estimated cumulative doses of I-131 they received from all atmospheric tests, as well as from individual tests. For example, a 3 to 5 month old infant who lived in Denver, Colorado during the Plumbbob test series conducted between May 28 and October 7 1957, would have received an estimated I-131 dose of 1.54 to 29.98 rads (with an estimated mean of 6.80 rads). This exceeds the NCRP recommended limit of 1.5 rads.

[29] Land memos, ATTACHMENT 2.

- In total, about 150 million curies of radio iodine were released to the atmosphere from the nuclear weapons tests.[31] This is more than three times the amount of radiation released from the Chernobyl accident (40-50 million curies).[32]
- High levels of fallout were not limited to those areas near the Nevada test site. In a number of areas of the U.S., including the Midwest, the northern plains and the Northeast, individuals received doses of I-131 to their thyroid that were comparable to, or in some instances even exceeded, the doses received by citizens living near the test site itself.[33]

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[30] Statement of Jan Beyea, Ph.D, Hearing before the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Committee on Appropriations, United States Senate, "Radioactive Fallout From Nuclear Testing At Nevada Test Site, 1950-60," 105th Congress, 1st Session, S. Hrg. 105-180, October 1, 1997, pp. 28-34.

"....Of great concern is that physicians should be alerted to watch for signs and symptoms of lesser diseases than thyroid cancer, namely autoimmune hypothyroidism, mild thyroiditis, and possibly hyperthyroidism incident to Graves disease. These diseases can be initiated by low to moderate radiation doses, the recent literature suggest, presenting themselves years after exposure..."

"...The extensive data collected on people living around the 1986 Chernobyl disaster show that radioiodine exposures at surprisingly low doses - between zero and 30 rads, mid-point equals 15 rads - leads to significant production of antithyroid antibodies. The dose response stays fairly flat as dose increases up to a few hundred rads suggesting that a susceptible subgroup exists that is sensitive to low doses. Now, the presence of antibodies alone does not necessarily imply any diseases are yet present in this population, neither autoimmune thyroiditis, nor autoimmune hypothyroidism, nor autoimmune hyperthyroidism. However, the presence of elevated thyroid antibodies is a well-known risk factor for chronic for chronic thyroiditis and hypothyroidism."

[31] The I-131 study, p. 2.20.

[32] Astakhova, Anspaugh, Beebe, et. al, "Chernobyl-Related Thyroid Cancer in Children of Belarus: A Case-Control Study," Radiation Research, number 150, p. 349.

[33] The I-131 study, pp. ES 2 and TS. 10. See, also, the maps of estimated thyroid doses in Chapter 8, "Estimated Thyroid Doses Resulting from Atmospheric Bomb Tests Conducted at the Nevada Test Site".

Table 1.1, p. 29, The NAS report, Table 1.1. ATTACHMENT 1.

Estimates of Thyroid Dose for Individuals Born on January 1, 1952 in Selected Counties
(95% Confidence Interval)
(Average Diet with Milk)

Locations Around the Country

Location (county/state)	2.5 percentile (Rad)	geometric mean (Rad)	97.5 percentile (Rad)
Wayne, Michigan	1.3	7.4	41
Fairfield, CT	2.1	11	56
St. Clair, IL	2.6	11	47
Aroostook, ME	1.7	10	60
Sedgwick, KS	4.4	17	66
Boise, Id	1.4	19	260
Meagher, Mt	2.5	43	750
Anderson, Tn	1.8	6.5	23
Washington, D.C.	1.2	5.0	21

Locations near the Nevada Test Site

Location (county/state)	2.5 percentile (Rad)	geometric mean (Rad)	97.5 percentile (Rad)
Washington, UT	2.5	23	211
Clark, NV	0.4	5.5	68

Source: SENES Oak Ridge, Inc

When the study and its results were released, two additional issues were raised:

- Most of the citizens in areas removed from the test site were not advised of their true exposure levels and the potential risks they suffered as a result of the testing until 1997, even though this important information was available to NCI as much as 7 years earlier.[34]

- The data contained in the report and subsequent analyses of those data raise the issue of what type of medical intervention, if any, should be undertaken by the government as a result of the data on doses and projections on impacts. It is at this stage that the issue of harm is appropriately addressed, because each specific choice has consequences and the challenge is to identify the option that produces the most benefits (in this case early prevention of thyroid cancer mortality and the alleviation of thyroid related diseases) with the least negative impacts (unnecessary medical interventions and the complications that result from those interventions). The appropriate level of assistance is currently being studied by HHS. At the time of the release of the I-131 study in October, 1997 the NCI contracted with the Institute of Medicine (IOM) and the National Academy of Sciences (NAS)to assess the public health and medical implications of the findings of the report and to recommend what steps, if any, should be taken in response.

In a report released on September 2, 1998, the IOM and the NAS determined that a program of systematic screening for thyroid cancer based on the NCI report would not be advisable for several reasons: the affected population could not be identified and there was no direct evidence that early detection of thyroid cancer through systematic screening improves survival or other health outcomes because screening has the potential to detect non-malignant nodules which may then be unnecessarily removed, and the form of thyroid cancer linked to radiation exposures has a high survival rate when detected in routine clinical practice without screening. Instead of systematic screening, the IOM/NAS recommended that HHS focus on a program of public information and education about the potential impacts of I-131 on the thyroid and thyroid cancer, the harms of screening, and the lack of evidence that it improves survival or health outcomes.[35]

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[34] One draft of the I-131 report contained an Executive Summary and a Technical Summary. One page of the Executive Summary (page ES.1) is dated 12 July 1990. One page of the Technical Summary (page TS.1) is dated July 14, 1990. Three pages in the Technical summary which contain maps, are undated. All other pages in the Executive Summary and the Technical summary contain the date June 29, 1990. Page TS.25 contains the following: "The highest thyroid doses, in the range from 5 to 112 rads, are estimated not only for the stable populations in counties of states close to the NTS, like Nevada and Utah, but also for populations in counties of states relatively far away from the NTS. Like Arkansas, Colorado, Idaho, Kansas, Missouri, and Montana." Draft NCI Report. ATTACHMENT 9.

[35] The NAS Report, p.ES-6.

III. FINDINGS OF THE INVESTIGATION

1. Researchers at the National Cancer Institute substantially delayed the release of the I-131 report, despite data that showed that significant numbers of children across the nation received doses of radiation that were much higher and posed greater health risks than previously believed.

As the significance of the report's information became clear, questions from the Congress and the public arose as to why the NCI did not release such important information much earlier. The Subcommittee staff was tasked with determining why it took fourteen years for the NCI to complete and release the report. Publicly available information as well as individual statements and documentary evidence obtained in the course of the subcommittee's review of this matter confirms that the report could have been released years earlier, but was delayed by the director of the study.

Documents show that the report was essentially completed in the 1991/1992 time frame.

In 1991, an interim report to Congress on the I-131 report was drafted by NCI for signature by the Secretary of HHS and transmittal to Congress. In the 1991 report, the Project Director - - Dr. Wachholz - - wrote:

> In summary, a final report on all aspects of Public Law 97-414 Section 7(a) except for an estimate of the risk of thyroid cancer in persons exposed to Iodine-131 is expected to be transmitted to the Congress in 1992. The possible availability of credible data to provide a risk estimate is not expected for another 2-4 years, and a report addressing this issue will be submitted as soon as the Working Group is of the opinion that it is reasonable and appropriate to provide a valid and credible estimate.[36]

Annual reports by the NCI's Division of Etiology indicated that the I-131 report would be published around 1993.

> The FY 1992 Annual Report stated:
> Activities associated with [estimates of exposures and doses received by the public] have been completed during the present reporting period, and final reports will be submitted during the next reporting period.[37]

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[36] Draft "Interim Report of the Working Group for Thyroid/Iodine-131 Assessments Section 7(a) of the Orphan Drug Act, Public Law 97-414, 1991," p. 5. ATTACHMENT 10.

[37] "Annual Report of Radiation Effects Branch, Chemical and Physical Carcinogenesis Program, Division of Cancer Etiology, National Cancer Institute, October 1, 1991 through September 30, 1992", Division of Cancer Etiology 1992 Annual Report, p. 1178. ATTACHMENT 11.

The FY 1993 Annual Report stated:
Activities associated with [estimates of exposures and doses received by the public] have been completed during the present reporting period and a final report has been prepared.[38]

The FY 1994 Annual Report stated:
Activities associated with [estimates of exposures and doses received by the public] have been completed during the present reporting period, and a final report has been reviewed prior to printing.[39]

The language on the status of the report in the FY 1995 Annual Report is identical to the language in the FY 94 Annual Report, but again the I-131 report was not issued.[40] No annual reports were issued after 1995.[41]

Even the Advisory Committee and task groups established to develop methodologies and produce data for the report were disbanded in the early 90's. The I-131Advisory Committee, specifically created to assist in the production of the I-131 report, was abolished in 1993. The NCI provided the following rationale for the abolition of the Committee:

> Because the charge to the Committee has been appropriately addressed in the conduct of its business, and because its significant accomplishments are now a matter of record, it is recommended that the committee terminate on the prescribed date. [September 15, 1993][42]

The Project Director informed the Subcommittee staff that the abolition of the I-131 Advisory Committee was part of a government - wide effort to reduce the number of advisory committees. Dr. Wachholz stressed he was not consulted about the decision to abolish the I-131

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[38] "Annual Report of Radiation Effects Branch, Chemical and Physical Carcinogenesis Program, Division of Cancer Etiology, National Cancer Institute, October 1, 1992 through September 30, 1993", Division of Cancer Etiology 1993 Annual Report, p. 1180. ATTACHMENT 11.

[39] "Annual Report of Radiation Effects Branch, Chemical and Physical Carcinogenesis Program, Division of Cancer Etiology, National Cancer Institute, October 1, 1993 through September 30, 1994", Division of Cancer Etiology 1994 Annual Report, p. 1212. ATTACHMENT 11.

[40] "Annual Report of Radiation Effects Branch, Chemical and Physical Carcinogenesis Program, Division of Cancer Etiology, National Cancer Institute, October 1, 1994 through September 30, 1995", Division of Cancer Etiology 1995 Annual Report, p. 944. ATTACHMENT 11.

[41] Information that no annual reports were produced after 1995 was supplied to the Subcommittee staff by NCI's Office of Legislation and Congressional Activities.

[42] Note "To: Sue Feldman, Subject: Program Advisory Committee Assessments, May 5, 1993" National Institutes of Health. This includes the assessment of the NCI Thyroid/Iodine 131 Advisory Committee. ATTACHMENT 12.

Advisory Committee.[43] Nevertheless, the record of the Committee's activities indicates that it had indeed completed its work before it was disbanded in 1993.

According to records and information supplied to the Subcommittee, the Advisory Committee met eleven times between 1983 and 1989.[44] After it met on October 6-7, 1989 it did not meet again until March 1993.[45] According to Dr. Andre Bouville, who was the primary author of the I-131 report, the Committee members were briefed at length on the report at the March 1993 meeting.[46] Afterwards, according to the author, the process for issuing the report was rather ministerial and involved very little science.[47]

Indeed, in November 1994, Dr. Bouville gave a presentation on the I-131 study to the International Workshop on Environmental Dose Reconstruction in Atlanta, Georgia. One section of Dr. Bouville's presentation reads:

> The study was conducted from 1985 to 1992. Practically all of the results have been available since 1992, since two years ago, but the report is still to come out, to be published.[48]

NCI Researchers Acknowledged Delays

Information collected during interviews with the primary author of the report, Dr. Andre Bouville, and the Project Director, Dr. Bruce Wachholz (also Chief of the REB at NCI) also indicate that the report could have been released years earlier. Information provided to the Subcommittee reveals that the substantive data and methodologies necessary to calculate all information necessary to fulfill the Congressional mandates regarding exposures and doses to the

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[43] Interview with Dr. Bruce Wachholz, July 10, 1998.

[44] The NCI was not able to supply minutes for all of the meetings. The information on the dates of the meetings is based upon the meeting minutes supplied to the Subcommittee by the NCI, a list of meeting dates supplied by NCI's Office of Congressional and Legislative Affairs, and a memo from Dr. Wachholz detailing his recollection of the meeting dates. The Subcommittee staff also searched the Federal Register to confirm the dates. All but one meeting was noticed in the Federal Register. The Subcommittee has minutes of the one meeting that was not noticed in the Federal Register.

[45] Ibid.

[46] Interview with Dr. Andre Bouville, July 7, 1998. The minutes of the Advisory Committee meeting of March 30, 1993 also reflect that a briefing on the report took place.

[47] Interview with Dr. Andre Bouville, July 7, 1998.

[48] "Thyroid Doses from Iodine 131 to the U.S. Population Resulting from Atmospheric Nuclear Weapons Tests Conducted at the Nevada Test Site" by Dr. Andre Bouville, International Workshop on Environmental Dose Reconstruction , November 16, 1994, Atlanta, Georgia. ATTACHMENT 13.

American public were available in the 1990/1991 time frame and perhaps earlier.[49] The evidence suggests that by 1990 the NCI had developed data indicating that individuals in some regions of the country far from the Nevada Test site received doses comparable to and, in some instances in excess of, those received by individuals near the Nevada Test Site.[50] Dr. Bouville informed the Subcommittee staff that all substantive work had been completed by October 1992 and that only ministerial functions (relating to editing, formatting information to provide individual dose information based upon date and place of birth, and printing) remained to be completed.[51]

Around that time, Dr. Bouville and Dr. Wachholz began to devote increasing amounts of time to other projects (the Chernobyl thyroid and leukemia studies that are described under point 5).[52] Dr. Bouville estimated that he spent only 20% of his time on the report in 1993.[53] A complete, final draft of the report was not provided to the Project Director until October, 1994.[54] However, internal NCI documents and interviews with both Dr. Wachholz and Dr. Bouville revealed that the draft went unreviewed for approximately two years.[55] Dr. Wachholz did not complete the review of the draft until approximately mid-1997.[56] There was, effectively, a three year period where almost no work was done on the report.

A 1997 memo prepared by Drs. Wachholz and Bouville reveals that between October 1994 and the release of the report in October 1997, a total of only 20 man months was devoted to the report.[57] It appears that most of the tasks performed during that period were extremely ministerial (e.g. formatting) and could have been performed simultaneously if adequate resources were devoted to the project.

Dr. Owen Hoffman, a witness at the hearing, is a scientist who served as a consultant to the NCI I-131 study. He also served as a consultant to the dose reconstruction study conducted for the area surrounding the Oak Ridge facility. Dr. Hoffman informed Subcommittee staff that the I-131 report was substantially done in the late 80's. By 1991, detailed data on dose/age groups/counties were prepared. On the basis of his first hand knowledge of the production of the I-131 report, he firmly believes the work could have been released much sooner than it was.[58]

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[49] This includes drafts of the study provided to the Subcommittee and interviews with Dr. Wachholz, July 10, 1998, and Dr. Bouville, July 7, 1998.

[50] Draft NCI Report, page TS.25. ATTACHMENT 9. See footnote 17 for complete explanation.

[51] Interview with Dr. Andre Bouville, July 7, 1998.

[52] Interviews with Dr. Bruce Wachholz, July 10, 1998, and Dr. Andre Bouville, July 7, 1998.

[53] Interview with Dr. Andre Bouville, July 7, 1998.

[54] Interviews with Dr. Bruce Wachholz, July 10, 1998, and Dr. Andre Bouville, July 7, 1998.

[55] Interviews with Dr. Bruce Wachholz, July 10, 1998, and Dr. Andre Bouville, July 7, 1998 and personnel records supplied to the Subcommittee by NCI.

[56] Ibid.

[57] Memo "To: Faye Austin, From: Andre Bouville and Bruce Wachholz, Subject: Fallout report, Date: September 24, 1997" NCI. ATTACHMENT 14.

All of this evidence strongly indicates that the critical data on exposure and dose (the two issues addressed in the NCI report) could have been available much earlier (perhaps 4 years or more) than the eventual release date of 1997, had the completion of the report been given priority within the REB and NCI.

What is less clear is why the project was not given a higher priority by the Project Director and his superiors within the NCI. Apparently the Project Director believed that completion of the project was not a high priority. A draft chronology prepared in 1997 by the two principal NCI researchers offers a number of explanations for the delay in the report. Among those includes the following: "1993 - The demise of the [Advisory] committee, plus the fact that there had been no inquiry regarding this project from outside the Division for almost nine years, provided a very strong indication that this effort was not very urgent or important to the NCI or others."[59]

Another internal NCI document addressing the issue of why it took so long to produce the I-131 report states:

> 1. It could have been done faster by giving it a higher priority in the face of other demands on the researchers' time. However, NCI did not recognize the intensity of public interest in this particular study and did not ensure that it maintained its priority when competing demands needed to be met.[60]

In addition, conflicting signals were being sent by the Project Director. As noted earlier, reports written by the Project Director that appeared in the annual reports of the Division of Etiology all predicted that the report would be published in the 1992-1993 time frame. The Subcommittee staff found no evidence that upper management within NCI ever followed up to see why those projections were not met.

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[58] Interviews with Dr. Owen Hoffman, June 22, 1998 and June 25, 1998.

[59] DRAFT "Recent History of the Preparation of the NTS Fallout Report", NCI. ATTACHMENT 15.

[60] DRAFT "II. Timetable/Tracking/Why Did it Take So Long , C. How could the study have been done faster? Are there other studies that have taken this long? Have you taken steps to ensure that this kind of delay does not occur again?", p. 5, NCI. ATTACHMENT 16.

2. The NCI neither involved the public in its study nor adequately responded to governmental requests for information developed through the study.

Whether it was due to bureaucratic inertia, or a lack of appreciation for the need to be responsive to the public's inquiries about these matters, NCI researchers did not adequately involve the public in the I-131 study. Although in a few instances the NCI cooperated with requests for data from the I-131 study before it was published, at almost every juncture, when officials received requests for information from the public, they responded in a manner which had the effect of limiting public access to the research effort and the data it generated. Some examples of the NCI's response to requests for information about this study are described below.

Congressional requests for information and/or assistance on this issue were resisted or delayed. For example, in December 1994, Senator Byron Dorgan wrote Energy Secretary O'Leary and requested that NCI, in collaboration with DOE and the North Dakota State Department of Health and Consolidated Laboratories, examine childhood mortality in northern plains states and in states exposed to heavier fallout from the nuclear weapons tests and estimate possible leukemia and thyroid cancers from the fallout.[61] Senator Dorgan's request was prompted by a study of health effects in North Dakota from weapons testing fallout that noted childhood leukemia mortality increased in North Dakota in the 1960's, and estimated that 3 to 4 cases of excess leukemia and 50 to 100 cases of excess thyroid cancer could have occurred as a result of the fallout.[62] The study was based on data NCI had collected in the course of the I-131 study and provided to North Dakota officials in 1994. Representatives of the NCI had also met with Senator Dorgan and North Dakota health officials to discuss the data and a draft of the North Dakota report.

Concerned that a draft response to Senator Dorgan by DOE had effectively committed NCI to address the issues raised in the Senator's letter, Dr. Wachholz wrote to NCI's Office of Legislative Affairs:

> . . . I don't appreciate the possibility of devoting and consuming Branch resources and personnel to a pointless effort of this nature (and insignificance) any more than (Chief of the Radiation Epidemiology Branch) Dr. Boice does; we all have more than enough to do of a much more productive nature, and I, too, hope that any further attention to this matter can be avoided. . .
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> . . . There may be perspectives other than science involved here, however, and ultimately the NCI response may be based on policy considerations and judgments as well as

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[61] Letter to the Honorable Hazel O'Leary, Secretary, U.S. Department of Energy, from the Honorable Byron L. Dorgan, December 23, 1994. ATTACHMENT 17.

[62] Ibid.

> scientific ones. In this context, all options deserve attention, whether or not they are desirable.[63]

Since NCI personnel had determined that it had not received a letter from Senator Dorgan and therefore had not received a direct request from the Senator to do any work, Dr. Wachholz suggested one possible answer to the question of whether NCI should perform the analyses requested by Senator Dorgan:

> If NCI chooses to be non-responsive to the senator, this question disappears (unless the issue is pursued by the senator at NCI, elsewhere in the U.S.G.. or at other institutions).[64]

Over the next 45 days, Dr. Wachholz negotiated changes in DOE's response to Senator Dorgan in order to avoid committing NCI to addressing the Senator's request. Although other Branch Chiefs and Division Directors were notified of the concerns of the REB Chief, there is no record of whether they provided any feedback. At the time these events were occurring, Dr. Wachholz had received the final and complete draft of the I-131 report, but did not begin to review it for nearly another year.

In 1996, the provision of information to an HHS Federal Advisory Committee was delayed. In May, 1996, a representative of the Advisory Committee on Energy-Related Epidemiologic Research (ACERER), an advisory Committee established by the HHS to advise on the research agenda in the area of ionizing radiation exposure and potential health effects resulting form the government's weapons activities, requested that NCI provide the committee with a full list of the Institute's radiation projects, and specifically mentioned the I-131 study and studies related to Chernobyl.[65] When NCI had not responded by August, a second request was forwarded.[66] NCI provided a response in September 1996 that failed to mention the I-131 and Chernobyl studies.[67] In March 1997, nearly 10 months after the first request and 7 months after the second request, NCI provided a brief description of its work on the Chernobyl studies and acknowledged that it was working on the I-131 report, but provided no substantive information on the findings.[68] A chronology prepared by the NCI for its own internal review of the matter indicates that the Chief of the REB had been notified of, and provided documentation on, ACERER's request in late September 1996.[69] An internal memo written by Dr. Wachholz also confirms that he was notified of the request to provide information of the I-131 work, but that he "...unfortunately, neglected to do this. . ."[70] Therefore, a government advisory committee's request for information about a major report went unanswered for 10 months.

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[63] Cover note to "Betsy [Duane]" from "Bruce [Wachholz]", January 31, 1995. ATTACHMENT 17.

[64] Memorandum "From: Chief, Radiation Effects Branch, Subject: Some thoughts on your draft 'Request for Followup Information on Radiation Fallout Data' in anticipation of a letter of request from Senator Dorgan that has not yet been received, To: Betsy Duane, NCI", January 31, 1995, p. 3. ATTACHMENT 17.

[65] Letter to Dr. Richard Klausner, Director, NCI, from Mr. Tim Connor, May 1, 1996. ACERER resolution attached. ATTACHMENT 18.

[66] Facsimile transmission to Ms. Nancy Burgoyne, National Cancer Institute, from Mr. Tim Connor, August 2, 1996. ATTACHMENT 18.

[67] Letter to Tim Connor from Dr. Joseph F. Fraumeni, Jr., Director, Division of Cancer Epidemiology and Genetics, NCI, September 11, 1996. ATTACHMENT 18.

The Senate Minority Leader, Senator Tom Daschle, also experienced difficulty in obtaining data related to the weapons test fallout as late as the spring of 1997. On April 14, 1997 an aide to Senator Daschle contacted HHS to report that in late February, the Senator's office had asked NCI to provide information about the findings and management of the I-131 study, including whether any data had been compiled on the health effects of I-31 fallout from the Nevada Test site; what analyses and/or conclusions had been reached on that data; whether any report on that data had been drafted; and whether it would be possible to obtain the latest draft of the report. As the staff wrote in a memo to HHS:

> . . . We were first contacted about this issue in February, which is when I began talking to NCI. Dr. Bruce Wachholz (NCI) and I exchanged several messages without speaking to each other. In the meantime, [NCI legislative affairs] got involved and became my main NCI contact. [NCI legislative affairs] and I have spoken a number of times, and [legislative affairs] has been quite helpful. Nevertheless, we have been unable to obtain satisfactory answers regarding the Secretary's efforts to respond to P.L. 94-114 (sic).
>
> . . . [NCI legislative affairs] confirmed that a comprehensive 1,200 page report is 'in clearance' now. [NCI legislative affairs] says it is primarily a 'user' guide for the data, containing formulas that researchers and other can use to calculate county exposure figures. [NCI legislative affairs] maintains there are no conclusions or summary statements in the report."[71]

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[68] Letter to Jim Smith, Chief Radiation Studies Branch, Centers for Disease Control and Prevention (CDC), from Dr. Bruce Wachholz, Chief, Radiation Effects Branch, NCI, March 10, 1997. ATTACHMENT 18.

[69] "Centers for Disease Control and Prevention, Advisory Committee on Energy- Related Epidemiologic Research, Request for Information on I-131 Fallout Study, Major Actions" NCI, 9/25/97. See entry for 9/25/96: "E-Mail from Dr. Land to Ms. McClave requesting that a copy of DCEG's response be given to Dr. Wachholz, who would append the letter to include activities of the Radiation Effects Branch, DCB. Copies handcarried that day." ATTACHMENT 18.

[70] E-Mail to Betsy Duane, NCI Office of Legislation and Congressional Activities, from Dr. Bruce Wachholz, September 16, 1997. ATTACHMENT 18.

[71] Memorandum "To: Rich Tarplin, Dept. of Health and Human Services, From: Cybele Bjorklund, Office of Senator Tom Daschle, Date: April 14, 1997, RE: Iodine 131 inquiry", supplied to the Subcommittee by NCI. ATTACHMENT 19.

Documents made available to the Subcommittee indicate that by 1997 there were several drafts of the I-131 report, and at least two drafts contained executive and technical summaries. However, none of the versions of the report, and none of the executive and technical summaries, addressed the issue of health effects of I-131 from the Nevada Test Site.[72]

Dr. Klausner, Director of NCI since 1995, informed the Subcommittee staff that it was the memo from Senator Daschle's staff that alerted him to the long delay involving the I-131 study and that he subsequently took action to issue the final report.[73]

In a follow up communication to the NCI Director in August, Senator Dashle characterized the potential impacts of NCI's delay in releasing the report, both to public health and to the credibility of NCI:

> . . . The events leading up to and surrounding the release of the National Cancer Institute's (NCI) study of I-131 raises serious questions about NCI's commitment to its statutory mandate to investigate, on a timely basis, the health impact of I-131 fallout.
>
> . . . Fifteen years later, that public mandate is still unfilled. Fifteen years later - more than 40 years after the initial tests - those exposed to the tests have virtually no information about the probable impact of the tests on their health or the steps they should be taking to protect their health. Given NCI's proper emphasis on early detection of cancer and other illnesses, this situation is especially troubling.
>
> . . . The stakes are too high to allow this situation to be perpetrated, or to repeat itself. A delay in the delivery of crucial health information has the potential to manifest itself in very real health consequences. In this case, potentially exposed persons have neither the direct health information they need nor precautionary health guidelines that could serve them in the absence of such direct information. Furthermore, inordinate delays such as those that have plagued this study have a serious corrosive effect on public confidence in the government's commitment to providing them with timely, objective scientific information and protecting their health interests.[74]

There were other costs to NCI's lack of communication. Contrary to the observations by the NCI researchers that there was little demonstrable public interest in the results of the study in the late 80' s and early 90's, there were significant policy decisions being made that could have benefitted from the information being generated in the NCI study. However, none of the critical information being developed by the NCI was made available to that process.

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[72] Drafts of the I-131 report dated 1990 and 1994 both contained executive and technical summaries. See footnote 34 for additional information.

[73] Interview with Dr. Richard Klausner, September 3, 1998.

[74] Letter from the Honorable Tom Daschle to Dr. Richard Klausner, Director, NCI, August 27, 1997, Hearing before the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Committee on Appropriations, United States Senate, "Radioactive Fallout From Nuclear Testing At Nevada Test Site, 1950-60," 105th Congress, 1st Session, S. Hrg. 105-180, October 1, 1997, pp. 58-59.

Notwithstanding the lack of a final report on I-131 fallout from NCI, in 1990 Senator Orrin Hatch and other Senators from Utah, Arizona and Nevada sponsored legislation that presumed the fallout from nuclear testing caused excess cancers and acknowledged that their constituents were unwitting participants in the tests and that their health was put at risk. Other members of Congress obviously shared and supported the concerns that Senator Hatch and others had about the effects of nuclear weapons testing on the health of citizens in Nevada, Utah and Arizona, because they overwhelmingly enacted legislation providing compensation for uranium miners and individuals who lived in particular counties of Nevada, Utah, and Arizona for certain lengths of time (1 to 2 years) between 1952 and 1958 and in 1962, and contracted leukemia or other "specified diseases," including thyroid cancer.[75]

What Congress did not know, and the Subcommittee's investigation revealed, was that at that very same time the NCI had accumulated the data and identified the fact that many citizens (particularly those who were children during the testing period) in many other parts of the nation received doses of radiation as high or almost as high as those received by some of the citizens in Utah, Arizona and Nevada.[76] We now know that many members of Congress may still have constituents who had the same levels of exposures and have the same degree of increased risk as citizens in Utah, Arizona and Nevada and yet were not afforded equitable consideration under the law. In fact, because of the delay in the release of the NCI data, similarly-situated citizens in other parts of the country did not even receive a timely notification that they faced increased exposures and risks.

NCI's misunderstanding about the public's interest in this report may have been avoided if the NCI had included a public representative on the Advisory Committee established to address this matter. The documentation assembled in connection with the extension of the appointments of Advisory Committee members in 1991 noted the following: "due to technical nature of committee, lay representation is inappropriate."[77] If nothing else, the presence of some non-technical citizens on the Advisory Committee could have reminded the other members of the Committee and NCI researchers that the study was of great interest and importance to the American public and that the Committee had a duty to complete and release the report as soon as possible.

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[75] Radiation Exposure Compensation Act, P.L. 101-426, 104 STAT. 920, 42 U.S.C. 920 (October 15, 1990).

[76] Draft NCI report, page TS.25, Attachment 3. See footnote 34 for further explanation. In addition, communications between the Department of Justice, the NCI and the Radiation Effects Branch indicate that officials of NCI and the Radiation Effects Branch were aware of the compensation proposal being considered by Congress. In February, 1990 the Chief of the Radiation Effects Branch had commented on the Justice Department's position paper on the legislation. ATTACHMENT 20.

[77] Memorandum "Date: April 5, 1991, From: Annette McLaughlin, Dr. Richard Adamson's Office, Subject: NCI Thyroid/Iodine-131 Assessments Committee, To: Dr. Wachholz/Lorraine", NCI.. ATTACHMENT

In addition, the Advisory Committee did not fulfill the public information requirements of its charter. The Committee was required to meet at least twice annually.[78] Meeting records provided to the Subcommittee show that the Committee met only once in 1984, 1985, 1987, 1989 and 1993 and did not meet at all between 1990 and 1992.[79] The Committee was also required to issue annual reports on its activities.[80] The Subcommittee staff was able to locate only one annual report produced by the Committee (in 1985). Given that it did not even meet for three years, it is unlikely the annual report requirement was fulfilled.

3. HHS and NCI management performed little oversight or tracking of the project. As a result, they failed to ensure that the report was completed in a timely fashion and that important issues were addressed in an open manner.

There is no evidence that anyone at HHS or anyone other than those engaged in the project at NCI provided any systematic oversight of the study or the progress of the report. There are no records to indicate that major decisions affecting the project - - such as the decision to abandon efforts to address risk, or to shelve the I-131 work for work on Chernobyl - - were ever reviewed or approved by anyone above the Branch Chief, who was directing the study.

Although it was the recipient of the congressional mandate to perform the I-131 study, the HHS did not systematically track the progress or management of the report. In fact HHS failed to deliver to Congress an interim report on the progress of the study, even though it was required by law.

In a 1986 memo, the Acting Assistant Secretary for Health informed the Director of NIH that a report on the study was due to Congress in January 1984. However, "[a]n interim report was submitted to the office of the Secretary in August 1984 but not to the Congress."[81] The

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21.

[78] Charter, NCI Thyroid/Iodine-131 Assessments Committee, NCI, June 12, 1984, p. 2. ATTACHMENT 22.

[79] See footnote 44.

[80] Charter, NCI Thyroid/Iodine-131 Assessments Committee, NCI, June 12, 1984, p. 2. ATTACHMENT 22.

[81] Memorandum "Date: May 8, 1986, From: Director, Executive Secretariat, Subject: Report on Iodine 131 Assessment, To: Dr. Bruce Wachholz", HHS. ATTACHMENT 23.

Assistant Secretary then requested that NCI submit another report so that it could be forwarded to Congress.

Even as the congressional mandate for the study passed the decade mark, and as the projections for imminent release of the report included in NCI Annual Reports continually went unfulfilled, there were no inquiries from HHS regarding the status of the study and the projected timing for its release. The only contact between HHS and NCI on this matter appears to be the interim reports forwarded to HHS for delivery to Congress in 1984, 1986 and 1991. Thus, the Department effectively lost track of the report. More active oversight by HHS and a Departmental commitment to delivering the report to Congress in a timely fashion may have inspired NCI to give more attention to the status and management of the report.

The NCI hierarchy also failed to track systematically the progress of the project. There is no evidence that NCI management personnel above the Radiation Effects Branch Chief, Dr. Wachholz, including Division Directors, actively followed the management or progress of the study or took any action to ensure that the REB remained focused on the project until it was completed.

It appears that the only oversight mechanisms were the annual reports prepared by the REB Chief, which in the 1990's continually reported that the report was complete and printing was imminent. In fact, the NCI Director informed the Subcommittee staff that he only became aware of the long delay in the release of the report after the April 1997 information request from Senator Daschle's office, and it was only through his personal intervention that the report was put on a fast track for release and the decision to compile a risk estimate was made.

NCI management was apparently so indifferent about the long delays that in 1997 the REB Chief - - the one who directed the I-131 study - - was praised for his efforts in securing the release of the report.[82]

4. The report does not meaningfully inform the American public of the impacts of the radioactive fallout from the weapons testing program.

The presentation of data in the NCI study does not adequately inform the public of the magnitude and the relative impact of the fallout from the weapons tests and gives little attention to the subgroups of the population that are estimated to have received much higher doses of radiation.

For example, the data reveals that 3.5 million children who were under 1 year of age in

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[82] Personnel records made available to the Subcommittee by the NCI.

1952 received an average cumulative dose of 10.3 rads of fallout from the tests.[83] Children in nearly 920 counties were estimated to have received doses between 10 and 30 rads.[84] An additional 14 million children who were between the ages of 1 and 4 in 1952 received an average cumulative dose of 6.7 rads.[85] The maximum infant thyroid dose was estimated to be approximately 100 rads.[86] Yet in the Executive and Technical Summaries of the report, the NCI highlights the fact that the national per capita average thyroid dose was 2 rads and then states that, for any particular test, the thyroid doses for children between the ages of 3 months and 5 years exceeded the average per capita dose by a factor of about 3 to 7.[87] Only in the maps contained in Chapter 8 of the text and in the sub-annexes of the report located on NCI's web site can the public obtain information providing a rough estimate of their individual cumulative dose, and understand how that might have been affected by their age and diet.[88]

This lack of emphasis on dose information for those groups that would be at the highest risk is compounded by the failure of the report to provide estimates of risk that would enable Americans (especially those in the high dose/high risk subgroups) to understand how the doses they received might impact their health.

Despite a specific Congressional mandate to estimate the risk to the American public posed by I-131, the Advisory Committee's risk task force stopped meeting, and work on risk ceased, in the 1989/1990 time period.[89] Interviews with researchers for the study have turned up no evidence that any formal decision was made by the Advisory Committee, the NCI or HHS to halt further work on risk, even though it was specifically mandated by Congress.[90] It was not until the NCI was about to release its report that the Director of the NCI, Dr. Klausner, determined that a risk estimate should be performed.[91] The original estimate, the results of which were printed in a press release, estimated that the fallout would lead to an additional 10,000 to 75,000 excess thyroid cancers.[92] That estimate was subsequently revised to the range of 11,000 to 212,000 excess thyroid cancers.[93] Interviews with NCI personnel and other scientists indicate that risk estimates could have been calculated throughout the study, as soon as dose estimates were available. This was obviously a critical element of the study and the Congressional mandate, because without it, the estimates of exposures and doses are not meaningful to most Americans.

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[83] Land memos, ATTACHMENT 2.

[84] The I-131 study, Figure 8.25, p. 8.17.

[85] Land memos, ATTACHMENT 2.

[86] Testimony of Dr. Richard Klausner, Hearing before the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Committee on Appropriations, United States Senate, "Radioactive Fallout From Nuclear Testing At Nevada Test Site, 1950-60," 105th Congress, 1st Session, S. Hrg. 105-180, October 1, 1997, p. 12.

[87] The I-131 study, p. ES. 2.

[88] The I-131 study, Chapter8. See, especially, the maps included as Figures 8.1 through 8.68.

[89] Draft reports of the risk task group made available to the Subcommittee ceased in the 1988/1989 time period. A Chronology prepared by NCI indicates that there was a "discussion of animal studies to determine thyroid cancer risk from I-131 exposure" at the June 1990 meeting of the Division of Cancer Etiology's Board of Scientific Counselors. The Subcommittee staff did not find any later records of work on the issue of risk as part of the I-131 study. "I-131 Fallout Report and Collateral Activities Chronology", NCI. ATTACHMENT 24.

[90] Interviews with Dr. Bruce Wachholz, July 10, 1998 and Dr. Charles Land, July 14, 1998.

In a letter to Senator Daschle, the Director of the NCI explained that the study did not address risk because the data available to link I-131 fallout to specific cancers was not conclusive; there was no established risk coefficient for I-131 and thyroid dose exposure; and it was hoped that data from studies of health effects of the Chernobyl accident and epidemiologic studies of I-131 exposures in the Hanford, Washington area would be sufficient to provide an estimate of risk.[94] The Project Director, Dr. Wachholz, offered a similar explanation to Subcommittee staff.[95]

While the response was technically accurate, it did not address the real issue: whether there was some way of responsibly informing the American public on the potential health impacts of the weapons tests fallout. Dr. Klausner's letter implies that was not possible. That response appears inconsistent with what NCI and other researchers have told the Subcommittee staff and what the NCI itself actually did on this matter.

In fact, when the report was released, NCI included a risk estimate in an information packet that accompanied the report.[96] At that time, the NCI estimated that 10,000 to 75,000 individuals may develop fallout-associated thyroid cancers as a result of the testing.[97] A revised estimate was presented to the National Academy of Sciences in December of 1997. The NCI now estimates that 11,000 to 212,000 persons may develop thyroid cancer associated with the fallout.[98] Dr. Klausner informed the Subcommittee staff that it was he who ordered NCI to produce a risk estimate based on the exposure and dose data generated by the I-131 report.[99]

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[91] Interview with Dr. Richard Klausner, September 3, 1998.

[92] "Questions and Answers on the NCI Fallout Report", NCI, August 1, 1997.

[93] Land memos, ATTACHMENT 2.

[94] Letter from Dr. Richard Klausner, Director, NCI to the Honorable Tom Daschle, September 30, 1997, included in Hearing before the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, Committee on Appropriations, United States Senate, "Radioactive Fallout From Nuclear Testing At Nevada Test Site, 1950-60," 105th Congress, 1st Session, S. Hrg. 105-180, October 1, 1997, pp. 56-58.

[95] Interview with Dr. Bruce Wachholz, July 10, 1998.

[96] "Questions and Answers on the NCI Fallout Report", NCI, August 1, 1997.

[97] Ibid.

Dr. Charles Land of NCI performed the risk estimate at the direction of Dr. Klausner. Dr. Land informed the Subcommittee staff that it is always possible to perform a risk assessment once the exposure and dose to an individual are known. As he noted, the key is to make sure to identify the uncertainties associated with such an estimate so the public understands the limitations of the estimates. According to Dr. Land, the estimate he conducted for the NCI study could have been completed in 1995.[100]

Other scientists interviewed by the Subcommittee staff echoed Dr. Land's view, that the science necessary to estimate risk (with proper caveats that are always part of such estimates) was well known, and data from other scientific studies, such as growing data from research on the impacts of the Chernobyl accident, increasingly suggested a linkage between the amount of internal dose of I-131 and thyroid cancer, perhaps to the same degree as external I-131 radiation and thyroid cancer (for which there existed risk coefficients).

The very fact that the NCI itself published the risk estimate indicates there was a way to responsibly address the mandate. However, the risk estimate was performed only a few weeks before the summary of the report was released to the public in August of 1997. Therefore it was not possible to incorporate the estimate into the report and the committee missed an opportunity to fully integrate the estimates with, and provide context to, the information presented on exposures and dose. Without properly explained risk estimates, neither Congress nor the public received a portion of what Congress had mandated in 1983 - - an explanation of how fallout from the nuclear weapons tests may have ultimately affected the health of the American public.

The Project Director acknowledged in 1995 that it was possible to complete risk calculations based on the exposure and dose data from the report. In an internal memo assessing a request by Senator Dorgan to perform some mortality studies and risk assessments in the northern plains states that received high levels of weapons test fallout, Dr. Wachholz wrote:

> The estimation of leukemia and thyroid cancer presumably also can be estimated even though the results may have little scientific meaning because of uncertainties, assumptions, extrapolations, etc...

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[98] Land memos, ATTACHMENT 2.

[99] Interview with Dr. Richard Klausner, September 3, 1998.

[100] Interview with Dr. Charles Land, July 14, 1998.

> I understand also that there exist risk coefficients that can be applied to these dose values for both thyroid cancer and leukemia. While there is no accepted risk coefficient for thyroid cancer resulting from exposure to I-131, the National Council on Radiation Protection and Measurements (NCRP) has published guidance on this matter. The NCRP relates this coefficient to the risk of thyroid cancer following exposure to external radiation, the most recent analysis of which is in press and authored by eight scientists, five of whom are on NCI staff. Again, there are large uncertainties in estimating thyroid cancer cases from fallout, but presumably it could be done...
>
> Finally, the North Dakota Department of Health already has made estimates of fallout-related leukemia and thyroid cancer based upon dose and risk information provided by Drs. Bouville and Land. It might raise questions of NCI responsiveness to now say that the same could not be done for other states...[101]

Finally, the NCI had been advised that the data it had accumulated on fallout yielded risks that were much higher than anticipated. In 1996 Dr. Owen Hoffman, a witness at the hearing, provided the lead researchers at NCI with the preliminary results and conclusions of the Oak Ridge dose reconstruction study, which indicated that the fallout from the weapons tests posed a risk to citizens as far away as Tennessee. In the 1996 draft report, Hoffman and his colleagues estimated that for counties around Oak Ridge, Tennessee the median cumulative doses of I-131 from weapons testing fallout were 2.5 - 4.7 rads for children drinking commercial milk and 4.3 - 6.7 rads for children drinking milk from backyard cows.[102] Yet, there was no response from NCI until after the I-131 study was released, and no indication that the NCI speeded up efforts to get out its results or gave more attention to the issue of risk based on the findings from the Oak Ridge study.

For some time it had been possible to provide a risk estimate similar to the one Dr. Land eventually performed right before the release of the I-131 study, albeit with likely higher degrees of uncertainty. During the early to mid-1990's, as additional information regarding the link between thyroid cancer and I-131 emerged as a result of data from the Chernobyl accident, the estimate could be developed with less uncertainty. By 1995, this information was available to perform the assessment Dr. Land produced in 1997.

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[101] Memorandum "From: Chief, Radiation Effects Branch, Subject: Some thoughts on your draft 'Request for Followup Information on Radiation Fallout Data' in anticipation of a letter of request from Senator Dorgan that has not yet been received, To: Betsy Duane, NCI", January 31, 1995, pp. 1-2. ATTACHMENT 17.

[102] The assessment provided to NCI projected that doses attributed to I-131 fallout from the atmospheric weapons tests may result in a median of 3.4 in 10,000 to 6.1 in 10,000 total excess lifetime cancers for those drinking commercial milk and 5.7 in 10,000 to 8.5 in 10,000 total excess lifetime cancers for those drinking milk from a backyard cow. "First Iteration Dose and Health Risk Assessment for Iodine-131 Emissions from X-10 Radioactive Lanthanum Processing, April, 1966, Table 11.12, p. 11-13. Facsimile transmission "TO: Andre Bouville and Bruce Wachholz, FROM: F. Owen Hoffman, Subject: Attached Report, Date: May 2, 1996". On the cover of the fax, Dr. Hoffman wrote: "Attached are the preliminary results and conclusions drawn from our work to date. We calculated doses for Tennessee children from the Nevada Test Site fallout that are equal to the median children in Utah. I don't have an explanation for this. A copy of the full report is being sent to you and I would appreciate any comments. " ATTACHMENT 25.

The absence of risk estimates, combined with the focus on average per capita doses received across the nation, does not convey the impact of the fallout from the tests on the most vulnerable segments of the population at the time of the tests - - those who were small children. Estimates based on the data contained in the NCI report reveal the following impacts to those Americans who received high doses of I-131 as children.[103]

* Of the 3.5 million children who received an average cumulative dose of 10.3 rads, 2,300 to 43,000 may develop thyroid cancer as a result of the fallout.

* Of the 14 million children who received an average cumulative dose of 6.7 rads, 6,200 to 116,000 may develop thyroid cancer as a result of the fallout.

These figures provide a much more meaningful picture of the potential impact of the weapons tests and reveal that at least for some groups the fallout from the tests could potentially have a much more significant impact on their health than is portrayed in the NCI report. Unfortunately, such analyses were not included in the NCI report. While the numbers shown above are statistically small numbers compared to the 160 million Americans who were affected by the tests, the numbers represent people whose lives were involuntarily and unknowingly impacted by activities that the government knew or strongly suspected to be harmful, yet made a determination to provide no warnings or guidance that would enable Americans to take actions to protect themselves. In this context, even 3.5 million is a high enough number to warrant enough concern to at least provide meaningful and complete information in a timely fashion. This did not happen with the I-131 report.

5. The management failures of the I-131 study have been repeated in a NCI-led international effort to study the effects of radioactive iodine releases on thyroid cancer in the areas surrounding the Chernobyl nuclear power plant.

Like the I-131 report, the Chernobyl projects suffer from a number of repeated managerial failures. Those failures have resulted in delays in the projects and may possibly have caused irreparable damage to important international health studies.

Some of the most ambitious and important health effects studies ever undertaken, the

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[103] The figures were developed by the Subcommittee staff employing the figures and formulae included in the Land memos. As noted in footnote 6, the average thyroid doses for various age groups used in the Land analysis were developed by Dr. Andre Bouville, primary author of the report, based on data generated in the study. However, those doses do not appear anywhere in the report. ATTACHMENT 2.

Chernobyl projects encompass three separate studies - - a study of leukemia among Chernobyl clean-up workers and two thyroid studies, in Belarus and Ukraine, of children exposed to I-131. The thyroid studies are envisioned to last thirty years and consist of repeated examinations of 15,000 subjects in Belarus and 50,000 subjects in the Ukraine. The leukemia project in the Ukraine is currently in an 18 month pilot phase that will culminate in a decision whether it is scientifically and technically feasible and to move forward with a long term study. It is hoped that the studies will provide critical information regarding the correlation between the dose of I-131 received and the risk of the development of cancer. The operational and scientific details of each study are enumerated in a scientific protocol that was signed by the United States and the host government.[104]

The projects are part of a much larger cooperative effort between the United States and a number of former Soviet Union countries to explore a number of health, environmental and technical issues related to nuclear power. In 1990, DOE asked NCI to assume leadership of the Chernobyl studies and the two agencies entered into an Interagency Agreement (IAG) in 1991.

Under the best of circumstances, the Chernobyl studies would have been incredibly challenging for any organization. They are ambitious, complex projects operating under conditions that include political changes in the region, poor record keeping, difficulties in importing equipment for the studies, and difficulties in the different working methods and understanding of the scientists from the countries involved.

Notwithstanding these very real challenges, management of the study, by the same branch of the NCI responsible for the delayed I-131 report to the Congress, has been poor. As discussed below, this has resulted in years of delay, criticism by scientists, including some within the NCI, and concern by a major funding source of the project. Management of the Chernobyl studies has been characterized by inadequate budgetary and management planning, failure to share information and delegate responsibilities, delays in making critical decisions and a four year failure to appoint a five member advisory committee. The result is that the studies are years behind the schedule established in the protocols - - the only official long term planning documents in existence - - and they may be permanently affected as the loss of time increases the difficulty of locating the subjects for the study.

Problems have afflicted the studies from the start. Preparation of the protocols took a very long time. As a condition of the thyroid protocols, one of the first steps in the projects was to appoint within six months an advisory committee composed of five members from each country.[105] The bi-national committees were intended to oversee the integrity and pace of the studies and to make important decisions regarding budgeting, management planning and any necessary adjustments to the protocols.[106] The protocols call for an annual report to be made to the advisory committees for their consideration.[107] The U.S. peer review committees for both of the thyroid protocols highlighted the importance of the advisory committees and stressed the need to establish the committees as soon as possible. As the review committee for the Belarus thyroid protocol wrote to Dr. Wachholz, the U.S. leader for the projects:

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[104] "Scientific Protocol for the Study of Thyroid Cancer and Other Thyroid Disease in Belarus Following the Chernobyl Accident", (hereafter referred to as "the Belarus Thyroid Protocol."), 1994.

"Scientific Protocol of Thyroid Cancer and Other Thyroid Disease in Ukraine Following Chernobyl Accident", (hereafter referred to as "the Ukraine Thyroid Protocol."), 1995.

"Scientific Protocol for the Study of Leukemia and Other Hematologic Diseases Among the Clean-up Workers in Ukraine Following the Chernobyl Accident", (hereafter referred to as "the Ukraine Leukemia Protocol."), 1996.

> The second item which we wish to emphasize is the role of the oversight committee. Regardless of the anticipated difficulties in establishing the interactive function of this group and insuring its effectiveness and continuity, the reviewers embraced the long-term requirements of a scientific body that would be empowered to provide independent assessment of progress. The responsibilities of the oversight committee would be to review all aspects of the conduct of the research protocol so as to facilitate its progress and yield of validated clinical, pathological and epidemiologic information. The oversight group should be established as soon as possible so that the study may benefit from the advice and guidance of an interdisciplinary and bilateral scientific body of experts.[108]

When the Subcommittee staff interviewed NCI managers in July 1998, four years after the signing of the first protocol, the U.S. had not appointed its five members of the advisory committee.[109] The members from the other countries had been nominated years earlier, and concerns about the delay in the appointment of the U.S. members had been raised two full years earlier by DOE.[110] There is no evidence that anyone within NCI ever questioned the failure to appoint these crucial committees. The absence of these committees left a critical void in oversight and planning that has exacerbated many of the logistical and management problems now confronting the researchers.

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[105] The Belarus Thyroid Protocol, p. 11.1. The Ukraine Thyroid Protocol, p. 11.1. In the Leukemia project, an advisory group is to be established early in Phase II of the project. The Ukraine Leukemia Protocol, pp. 33, 35-36. Although the Leukemia Protocol was signed in October 1996, Phase I of the study, scheduled last 18 months, was not initiated until November-December 1997. Interview with Dr. Ihor Masnyk, August 20, 1998.

[106] The Belarus Thyroid Protocol, p. 10.1. The Ukraine Thyroid Protocol, p. 10.1.

[107] The Belarus Thyroid Protocol, pp. 11.1- 11.2. The Ukraine Thyroid Protocol, pp. 11.1- 11.2.

[108] Unsigned, undated letter to Dr. Bruce Wachholz, conveying reviewers' general and detailed comments on the Belarus Thyroid Protocol, p.2. Letter to Dr. Bruce Wachholz from Dr. David Schottenfeld. conveying reviewers' general and detailed comments on the Ukraine Thyroid Protocol, pp. 1-2.

[109] Interview with Dr. Bruce Wachholz, July 10, 1998.

[110] Letter from Dr. Elaine Gallin, Deputy Director of DOE's Office of International Health Programs, to Dr. Bruce Wachholz, February 15, 1996. ATTACHMENT 26.

The failure to appoint the advisory committees and the lack of oversight and involvement by NCI upper management has had the effect of transferring overall control of the U.S. portion of the study to the NCI's Radiation Effects Branch and its Chief, Dr. Bruce Wachholz. In the absence of the advisory committees, an advisory panel established by the NCI to help formulate the protocols and advise on the projects was abolished, necessary changes in the protocols have not been approved, no annual reports have been prepared, and no systematic review of the projects' status and problems has occurred. In sum, the Chernobyl studies are experiencing management failures reminiscent of the I-131 study.

Staff interviews and internal documents revealed that a number of scientists have been critical of the management style of the REB leadership. This includes scientists formerly associated with the project, those currently associated with the project and those located in other institutions. The scientists expressed concerns that the current management style is too slow to make decisions; does not adequately delegate authorities/responsibilities for decisions and communications that are important to move the project along; and does not communicate information in a timely fashion. Individuals currently associated with the project have also expressed frustration with the pace of the projects and one member of the NCI team had actually discussed circumventing the REB Chief in an attempt to resolve some of the problems in the projects with the Director of the Division that oversees the REB.

In 1996, officials from the Department of Energy, which provides approximately half of the funding for the Chernobyl projects, began raising concerns about the studies. In February 1996, Dr. Elaine Gallin, Deputy Director of DOE's Office of International Health Programs, wrote to Dr. Wachholz and identified the following concerns regarding the Belarus thyroid study: lack of an identifiable funding source to meet future costs as the project expands; the slow pace of the programs; failure to appoint an advisory committee; failure to share information; and failure to develop an overall management plan with clear milestones by which DOE could chart the progress of the study. Dr Gallin noted that DOE had "many similar concerns regarding the thyroid and leukemia studies in Ukraine."[111] The Subcommittee staff has seen no evidence that many of the problems identified by Dr. Gallin in that 1996 letter have been meaningfully corrected.

In 1996, for example, the thyroid projects were falling behind the schedule originally established in the protocols. The protocol for the Belarus thyroid study, which was signed in May 1994, called for the establishment of the advisory committee within the first six months, submission of an annual report to the oversight group by May 1995 and initiation of the examination of children according to the protocol by May 1995.[112] None of those objectives were accomplished in 1996. Indeed, two of the tasks are not complete today, and only 929 people have been screened. Delays and unanticipated events that affect scheduling are to be expected; what was surprising was the failure of NCI to have a detailed management plan with milestones and corresponding budget plans that would focus the project, pinpoint critical events and facilitate analyses of the project's status and potential trouble spots when schedules are missed. In fact, the Director of the Division of Cancer Biology (which includes the Radiation Effects Branch), the Chief of the Radiation Effects Branch and the U.S. Associate Director of the Chernobyl studies have stated to Subcommittee staff that the projects do not have detailed management plans, milestones or out-year budget estimates.[113] Without these elements, the project planning relies on quarterly milestones which makes it difficult to develop a long term plan and to determine whether any real progress is being made toward critical objectives.

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[111] Ibid.

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[112] The Belarus Thyroid Protocol, p. 11.1.

[113] Interviews with Dr. Faye Austin, Director of the Division of Cancer Biology, September 1, 1998; Dr. Bruce Wachholz, Chief of the Radiation Effects Branch, August 31, 1998; and Dr. Ihor Masnyk, U.S. Associate Project Director of the Chernobyl studies, July 16,1998 and August 20, 1998. At the request of the Subcommittee staff, the NCI provided the most current budget and planning documents. The milestone and management plans are little more than simple time lines with general goals and are not detailed planning documents. There are few details about specific tasks and sub-tasks, responsible parties and how various elements tie into each other. In addition, the milestone and management plans have different completion dates for identical tasks. Milestones for the limited, pilot phase of the leukemia study were revised in the May-July 1998 period. The more recent plans are more complete. Although FY 98 is nearly completed, the projects lack any budget projections beyond FY 2000, and there is no indication that the budget numbers that are available are tied into the milestone/ management plans. When asked if NCI had a 3 or 5 year budget plan for equipment and supplies, Dr. Masnyk informed the Subcommittee staff that NCI had attempted to develop one, but the effort was not successful because there was no track record with respect to purchases. He stated NCI could now make better projections because it had established a track record of equipment purchases. Dr. Masnyk also informed the staff that the project budget sheets provided to the Subcommittee represented figures he had put together in the 1996 time frame. They represented his best estimate of what was needed for the projects and that he had done little if any update work since that time. (Interview with Dr. Ihor Masnyk, August 20, 1998). Subsequent to those interviews, the subcommittee received another set of project budget sheets from NCI on September 10, 1998. Both sets of budget sheets are included in ATTACHMENT 27. The figures for the Belarus and Ukraine thyroid studies in the September 10 budget sheets are the same as the figures contained in the budget sheets previously provided to the Subcommittee. The figures for the Ukraine leukemia study were increased and, as a result, the combined budget for all three projects was also increased accordingly. However neither set of budgets accurately reflects what was spent on the studies in FY 96 or 97. In addition, the projections of DOE contributions for fiscal years 1999 and 2000 do not reflect what is actually available from existing contributions and future commitments. Most of the funds already contributed to NCI by DOE, NRC and IPSN (a French Institute) have been expended. (See GAO budget analysis, ATTACHMENT 33 for status of DOE funds. For a status of NRC and IPSN funds, see footnote 129 and ATTACHMENT 34.) With respect to future contributions, the current Interagency Agreement between DOE and NCI limits DOE's annual contribution to $800,000 (see ATTACHMENT 30), and neither the NRC nor the IPSN have committed to contributing any additional funds to the studies. Thus, the projections of DOE contributions of $1.9 million in FY 99 and $2.1 million in FY 2000 do not appear to accurately reflect realistic budget estimates for these projects given existing available funds and current funding agreements, even if the projected DOE contributions were assumed to include equipment and supply contributions from other agencies.

Sound planning is well-known to be an important part of a scientific study. After a 1985 peer review of a contractor-run epidemiology study of people in Utah who had been exposed to weapons testing fallout, Dr. Wachholz informed the contractor that there were concerns about the project. The analysis of the project's management included the following:

> . . . it is clear that there remains a lack of strong and effective day-to-day technical and administrative direction, little or no unity of effort, and no well-defined protocol with milestones leading to a successful and timely completion. This is particularly distressing considering the size, scope complexity, sensitivity and multi-disciplinary nature of this project.
>
> . . . Each of the project tasks requires a management plan, in writing, which is considerably more comprehensive than a simple time line. Specific and realistic goals for each component and activity of the project must be clearly identified as to purpose, protocols, methodologies, use, influencing factors, uncertainties, etc., including what is due, to whom it is due, when it is due and the person responsible for it, together with a master plan of how it all interrelates, including specific data analyses and presentation formats.[114]

However, REB management has not applied the same standards to the Chernobyl projects. The REB Chief explained to the Subcommittee staff that the conditions under which the Utah study was being conducted were quite different from the situation at the Chernobyl projects. The Utah study was taking place in the U.S., the cohort had been identified and located, and scientists in the project were familiar with the procedures and technologies employed in the study. Not only do very different conditions exist at the Chernobyl projects, but the U.S. managers are not running the studies. They are only involved to provide equipment and assistance/advice to the scientists of the host countries. For those reasons it was difficult to develop detailed management plans.[115]

NCI management cites the problems of coordinating this large project overseas as a major reason why it lacks detailed milestones and budgets and the progress is not as fast as might be hoped.[116] While there are uncertainties and coordination problems that may be a partial explanation for the slow pace of the studies, it would seem that such conditions would make it more important to have a plan to guide the project and measure progress. Moreover, the fact that the bi-national nature of the projects could impede the development of management and budget plans underscores the importance of establishing the advisory committees, which are charged under the protocol to address management, scientific and financial issues.

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[114] Letter to Dr. Walter Stevens, Associate Dean for Research, College of Medicine, University of Utah, from Dr. Bruce Wachholz, Chief, Low Level Radiation Effects Branch, NCI, (undated), including "Enclosure A, Summary of Reviewers' Comments on National Cancer Institute Contract NO1-CO-23917, 'Assessment of Leukemia and Thyroid Disease in Relation to Fallout in Utah'", pp. 1-2 of Enclosure A. NCI. ATTACHMENT 28.

[115] Interview with Dr. Bruce Wachholz, September 8, 1998.

[116] Interviews with Dr. Ihor Masnyk, U.S. Associate Project Director of the Chernobyl studies, July 16 and August 20, 1998 and Dr. Bruce Wachholz, August 31 and September 8, 1998.

If, however, the conditions under which the project is operating are so problematic that management plans, milestones and budgets cannot be developed, then there may be a need to reconsider the long term prospects for success and the soundness of our government's commitment to the project.

A resistance to sharing information similar to that found in the conduct of the I-131 study is also found in the ongoing Chernobyl studies. NCI has continually resisted sharing information about the Chernobyl project with DOE, even though the Department supplies nearly half of the annual costs of the project - - $800,000 . As noted above, this matter was raised by Dr. Gallin in a February 1996 letter to Dr. Wachholz. She noted that DOE was in need of such fundamental information as a progress report, an organizational chart, and a completed set of milestones that included clear deliverables for each task.[117]

The problem of information exchange apparently has not changed since that time. Even though the current Interagency Agreement and the corresponding funding agreement between DOE and NCI clearly specifies the information to be supplied to DOE - - standard management and financial planning documents and progress reports - - the DOE has had extreme difficulty obtaining it. In March 1998, DOE's Program Manager for International Health Studies met with NCI's U.S. Associate Project Director of the Chernobyl studies to explain what NCI's reporting responsibilities were, even though they were spelled out in a July 1, 1997 funding agreement between the two agencies.[118] Even after that meeting, all of the information was not supplied. In July 1998, when NCI requested that DOE provide its $800,000 annual contribution, the DOE Deputy Assistant Secretary for Health Studies informed NCI that the Institute had still not fulfilled its reporting requirements. The required documents and information were then supplied to DOE before it released the funds to NCI.[119] Given the lack of any outside oversight of the project, it remains puzzling why NCI would not welcome input from an outside source that has a financial interest in the success of the project.

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[117] Letter from Dr. Elaine Gallin, Deputy Director of DOE's Office of International Health Programs, to Dr. Bruce Wachholz, February 15, 1996. ATTACHMENT 26.

[118] Interviews with Dr. Ihor Masnyk, July 16, 1998 and August 20, 1998 and interview with Frank Hawkins, Director, Office of International Health Programs, Department of Energy and Mr. Barrett N. Fountos, Program Manager, Office of International Health Programs, Department of Energy, September 11, 1998.

[119] Interviews with Frank Hawkins, Director, Office of International Health Programs, Department of Energy, August 18, 1998 and September 11, 1998.

In addition to the difficulties encountered by DOE, Lawrence Livermore National Laboratory (LLNL), which procured equipment and supplies for the Chernobyl projects, experienced continual frustrations in its efforts to receive NCI guidance on how procurements should be prioritized, as well as final decisions on purchases of equipment and supplies. The LLNL personnel believe that failure to provide timely decisions slowed the program and resulted in a waste of some materials and supplies that had limited shelf lives.[120]

In the fall of 1996, after failed attempts to re-work the IAG to re-define the roles of NCI, NRC and DOE, DOE agreed to a new Interagency Agreement that gave NCI complete control of and authority for the Chernobyl studies.[121] Essentially, DOE - - concerned about management and the pace of the projects - - decided to remove itself from the operation of the project, although it continued to provide funding. In addition, LLNL withdrew from the projects at about the same time. That departure effectively set back procurement efforts by nearly 1 year.[122]

As with the I-131 study, NCI has not adequately managed these projects, and has been slow to respond to problems, despite clear signals that progress was slow and there were concerns about management issues. During 1996, DOE personnel communicated their concerns to the NCI Division Director responsible for the REB, but no action was taken immediately. As with the I-131 situation, only when the issue received repeated outside complaints did management take corrective action. As a result of a meeting with DOE personnel in July 1996, NCI's Director made a decision to solicit for a contractor to work on the studies and appointed another NCI employee as Associate Project Director, responsible for the administrative aspects of the project.[123] As with the I-131 study, it is commendable that the Director reacted, but there is a question why NCI officials below the Director level did not react sooner. In addition, it is unclear whether the actions taken by the Director will fully resolve the problems of the project.

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[120] See correspondence and E-mail between LLNL, NCI and DOE, included in ATTACHMENT 29.

[121] Interagency Agreement , FY 1997, Between the Department of Health and Human Services, National Cancer Institute, and The Department of Energy, Office of Environment, Safety and Health, February 19, 1996, p.1, I. B. 1 and 2. ATTACHMENT 30.

[122] LLNL withdrew from the project in September 1996. In May 1997 NCI finalized an agreement with the Veterans Affairs National Acquisition Center (VANAC) to perform the procurement functions for the Chernobyl projects. However, even then the procurement and delivery of equipment was slowed because of VANAC's inexperience in conducting operations of this nature. See memos and reports from Dr. Everett Mincey, Dr. Gilbert Beebe and Dr. Ihor Masnyk,, included with the NCI/VANAC Interagency Agreement as ATTACHMENT 31.

[123] Interview with Dr. Richard Klausner, September 3, 1998.

In the two years since the new DOE/NCI Interagency Agreement was signed, and the Director instituted his reforms, little progress on the Chernobyl studies has been made.

* More than 4 years after the Belarus thyroid protocol was signed, project researchers have confirmed contact with 3500 members of the 15,000 person cohort and have screened 2869 people. Three years after the Ukraine protocol was signed, researchers have confirmed contacts with 800 people of the 50,000 person cohort and have screened 529.[124] No examinations occurred prior to 1997, seven years after NCI began the studies and approximately three years after the signing of the Belarus protocol. The second in command of these studies views them as having essentially begun, respectively in December of 1997 and March of 1998.[125] To date, approximately $6.3 million has been obligated, and $5.6 million spent, on these projects.[126]

* There are concerns, evidenced in reports by NCI's contractor, Columbia University, and in NCI's own communications and reports, about locating the study cohort subjects for the thyroid studies in Ukraine and Belarus. In a technical report to the NRC dated July 22, 1998, the U.S. Associate Project Director wrote that researchers in both Belarus and Ukraine were having trouble locating cohort subjects.[127]

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[124] Presentation by Dr. Bruce Wachholz and Dr. Geoffrey Howe to the National Cancer Advisory Board, September 10, 1998. ATTACHMENT 32.

[125] Interview with Dr. Ihor Masnyk August 20, 1998.

[126] This consists of approximately $6.1 million in federal dollars and $250,000 from IPSN, an institute in France. Interview with GAO, September 1, 1998. Budget analysis prepared for Subcommittee by the General Accounting Office. ATTACHMENT 33.

[127] On December 15, 1997, Dr. Bruce Wachholz and Dr. Ihor Masnyk wrote the following to the Ukraine Director of the Ukraine American Thyroid Project: ". . . I cannot overemphasize, however, the importance of the message I conveyed to you at our last meeting - that this is a critical time, and that the level of continued future support will be determined by the level of progress that will be achieved by mid-1998. With the arrival of computers and other clinical and diagnostic equipment, as well as the previous receipt of a vehicle, there should be no reason why rapid progress in the implementation of the project cannot be made. . . . Although all aspects of the project are important, the highest priority, at the present time, should be given to the identification and location of the cohort. Unless an adequate cohort of subjects that will satisfy the objectives of the project is identified and located, we will have difficulty justifying continuation of the present joint study as we are under continued pressure to show results of our support. I would encourage you in the strongest possible terms, therefore, as we discussed in our meeting, that over the next 6-8 months every effort be made to identify and locate the cohort. . . . If the cohort is not adequate and the objectives of the study, as define in the protocol, are unlikely to be obtained, the NCI (together with the Department of Energy and the Nuclear Regulatory Commission) will need to reassess its commitment to and support for continuation of the current protocol." Letter from Dr. Bruce Wachholz and Dr. Ihor Masnyk to Professor Nikolai D. Tronko, Director, Research Institute of Endocrinology and Metabolism, Ukraine, December 15, 1997. A similar letter was sent to the Belarus Director of the Belarus American Thyroid Project. Letter from Dr. Bruce Wachholz and Dr. Ihor Masnyk to Dr. V. A. Stezhko, BelAm Thyroid Disease Project Director, Belarus, December 22, 1997. ATTACHMENT 34. Yet the problems identifying and locating the cohorts continued. In July

* While there is hope that Columbia University can facilitate and speed up activities and improve coordination, it is limited in the initiative it may take because it is a service contractor. Columbia University works at the direction of, and through, NCI. Further, staff of Columbia University told the Committee they entered into this contract with the understanding that Columbia would gradually assume control of the studies. If that does not occur, they will seriously consider whether they should pursue a renewal of the contract.[128]

* The lack of detailed management and budget plans still plague the projects. NCI officials informed the Subcommittee staff that equipment and supply funding for the projects is running out. NCI expects that there may be enough money to carry the thyroid projects through FY 99 and to complete the Leukemia pilot study. In a presentation made to the NRC in July 1998, NCI officials projected that the projects would have an equipment and supply funding shortfall of $235,000 in calendar year 1999, and a shortfall between $500,000 and $600,000 in calendar year 2000. [129] Project officials informed Subcommittee staff that they did not have out year budget plans for either equipment and supplies or operational activities.[130] The Subcommittee staff requested the documentation used to develop budget projections, but has not yet received that material.

* The advisory committees have still not been appointed or met, although members have finally been selected and their names have been submitted to other agencies for comment.

1998 Dr. Masnyk wrote the following about the efforts in Belarus: "Locating the study cohort subjects chosen from the list of children with measurements of thyroid radioactivity in 1986 is proving difficult." Regarding efforts in the Ukraine, he wrote: "As in Belarus, the investigators in Ukraine are having difficulty locating members of the cohort." Technical Report for the period 1 April 1998 to 30 June 1998, "Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and in Ukraine (UkrAM Project), Submitted by: Ihor J. Masnyk, Ph.D., Radiation Effects Branch, DCB, NCI, July 22, 1998", pp. 1 and 2. ATTACHMENT 34.

[128] Interview with Dr. Geoffrey Howe, Dr. Michael O'Connor and Dr. Richard Sohn, Columbia University, June 24, 1998.

[129] NCI presentation to NRC, July 6, 1998. ATTACHMENT 35. See also "Reporting Requirement on Interagency Agreement No. Res-97-001 'Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and in Ukraine (UkrAM Project),' AND 'Scientific Protocol for the Study of Leukemia and Other Hematologic Diseases Among the Clean-up Workers in Ukraine Following the Chernobyl Accident' (UkrAm Leukemia Project)," Submitted by: Ihor J. Masnyk, Ph.D., Radiation Effects Branch, DCB, NCI, July 22, 1998", p. 4. "It should be noted that there appear to be enough funds for the UkrAm Thyroid Project and only limited funds in BelAm Thyroid and UkrAm Leukemia projects. The leukemia activity should be adequately covered for the remaining period of the pilot phase; new funds must be allocated if the study should be extended to a full, long term project. The Belarusian thyroid project is in need of additional funds, especially if the anticipated expansion to the Gomel area is to be undertaken. The REB staff is currently searching for additional funds." ATTACHMENT 34.

[130] Interviews with Dr. Ihor Masnyk, July 16, 1998 and August 20, 1998 and Dr. Bruce Wachholz, August 31, 1998 and September 8, 1998.

The Chernobyl study is plagued not only by challenging international circumstances but also by poor management within a branch of the NCI, and the result has been a delay in the collection of important health-related information. Against this background of poor management, agencies threatening to cut off funding, scientists resigning over conflicts with NCI management, and the extraordinarily long delay in the initiation of the clinical phase of the studies, the upper management of NCI in 1997 gave an award and the NIH Director's award to the REB Chief, who is running these projects. The thyroid studies in Chernobyl are a unique opportunity to learn a great deal about the health effects of I-131 fallout. However, this opportunity is being threatened by management problems within NCI.

IV. CONCLUSION

NCI's handling of the I-131 study and the Chernobyl studies raises some fundamental questions about openness and management. These studies have also been jeopardized by management problems within the NCI. The I-131 study was delayed for at least 4 years and perhaps longer because the NCI did not give the project appropriate priority despite a Congressional mandate, clear signals of strong interest from the public and governmental entities, and a public health ethic to provide citizens with important health information in a timely fashion.

The studies of the health effects of the Chernobyl accident (particularly the two studies focusing on thyroid cancer in Belarus and the Ukraine) have been delayed far beyond expected time lines established in the International Protocols for the projects. Operations of the projects are threatened because they lack a secure source of funding for equipment needs beyond the next fiscal year. The projects also lack fundamental management tools - - intermediate/long term budget plans, and management and milestone plans - necessary for proper planning, coordination of activities and assessment of project status and problems. In these respects, the projects have not even met the management and planning standards that the NCI sets for its own contractors and grantees. Scientists formerly and currently associated with the project believe there has been a lack of timely decision making and a failure to delegate the authorities needed to facilitate daily operations of the projects.

As a result of these and other factors, it is uncertain whether the Chernobyl projects will be able to locate and screen the human participants (cohorts) that are so critical to the success of the studies. NCI recently hired Columbia University to serve as a contractor to the study. This may improve the operations of the project, and increase the pace of activities. However, Columbia is only a service contractor, operating at the direction of, and through, NCI. The fundamental problems with respect to planning and budgeting still remain.

The management of the REB has also displayed a reluctance to share information on the I-131 and Chernobyl projects with the public, states and federal entities in a complete and timely manner. The findings of the Subcommittee's investigation into this matter also raise a question whether the NCI appreciates the public's right to and desire for input into this area of health effects research. An appropriate level of appreciation for openness in fact may have assisted the NCI in placing priority on the progress of these projects.

The actions of NCI in these studies stand in stark contrast to the model that is now employed by the Centers for Disease Control and Prevention (CDC) to assess dose and health impacts of radiation releases from federal nuclear weapons plants. Those processes employ a high degree of openness and broad public participation. For example, the Memorandum of Understanding (MOU) between DOE and HHS governing the assessment of health impacts of DOE nuclear- related research and development activities places great emphasis on openness and public involvement in setting the research agenda and in the actual conduct of the studies. It establishes a federal advisory committee that includes public health officials, public interest groups and affected parties. Representatives of the population to be studied in any project are included on the review panel established to perform the study. Results are required to be promptly disseminated to affected groups and the general public.[131] The effort to widely disseminate information and include the public in the decision process has improved the credibility and public acceptance of the findings that result from those efforts.

The difference in public acceptance and credibility of the studies that have resulted from the CDC process compared with public reaction to the I-131 study underscores the value of public participation and openness.[132] Unfortunately, the process established through the MOU is limited to the studies covered under the agreement. Research initiatives instituted by or through other HHS agencies that are outside the MOU do not follow the guidelines and principles set forth in that agreement. The difference in the approach taken to this highly charged area of research by these agencies suggests the need for HHS to establish Department-wide policies and guidelines that will govern the approach to such work.

This is a matter that should be rectified as more research in this area is delegated to HHS and its agencies. Consistent application of the principles of openness and public participation will help to establish the credibility and public acceptance that has been absent in studies of this nature.

After growing for years, the problems recounted in this report eventually reached the level of the NCI Director. At that point, he intervened and took corrective actions. For example, as a result of the April 1997 letter from Senator Daschle, the Director took the initiative to ensure the report was released. It was the Director who ordered that a risk estimate be performed so Americans might have some idea of the potential impact of the weapons test fallout on their health. He instituted a tracking system that will follow important Congressional requests. He has started a program of interaction with the CDC to try to get more openness and public participation in the NCI work. He also delegated some of the management responsibility of the Chernobyl studies to an additional NCI employee and directed the Deputy Director of NCI to play an active role in a number of radiation health effects research activities. [133]

These measures are commendable. It is noteworthy, however, that the top official of the

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[131] " Memorandum of Understanding Between Department of Energy and Department of Health and Human Services" May 14, 1996. ATTACHMENT 36.

[132] Although many of these CDC projects concern a population of a defined geographic area, whereas the NCI's I-131 study concerned the entire country, a public representative on the I-131 study could have served a useful function in alerting NCI scientists to public concerns and issues related to the study.

[133] Interview with Dr. Richard Klausner, September 3, 1998.

Institute was required to intervene to resolve what should have been basic management activities and questions remain concerning the agency's approach to radiation health effects research. It is unrealistic, and an inefficient use of time and resources, for the Director, or his Deputy, to serve as the daily monitor of activities in the area of radiation effects research. Indeed, a number of serious management problems affecting the Chernobyl projects are still unresolved. Hopefully, some of the changes instituted by the Director will begin to effect some systemic improvements. The public interest would be better served by an institutional management that recognizes the importance of openness and public participation.

There is also a need for HHS to become more actively involved in these issues and take actions that will ensure that openness and good management are applied consistently throughout the Department in all of its radiation health effects research projects. To that end, the staff respectfully recommends that:

1. HHS should establish Department-wide policies and procedures to ensure openness and public participation in radiation health effects research, so that there will be consistency in the Department's approach to this important issue.

2. HHS should institute an independent management and scientific audit of the Chernobyl projects to identify the areas that warrant improvement in order to increase the chances of successful completion of the studies.

ATTACHMENT

1

TABLE 1.1 Thyroid dose (cGy) for an individual born on Jan. 1, 1952

Dietary source of Iodine-131	average diet with retail commercial milk.				average diet with milk from a "back yard cow"				average diet and milk from a backyard goat				average diet without milk			
	(95% Uncertainty Range)				(95% Uncertainty Range)				(95% Uncertainty Range)				(95% Uncertainty Range)			
Location (Co.)	2.5% tile	Geo. Mean	(GSD)	97.5% tile	2.5% tile	Geo. Mean	(GSD)	97.5% tile	2.5% tile	Geo. Mean	(GSD)	97.5% tile	2.5% tile	Geo. Mean	(GSD)	97.5% tile
(units)	(cGy)	(cGy)		(cGy)	(cGy)	(cGy)		(cGy)	(cGy)	(cGy)		(cGy)	(cGy)	(cGy)		(cGy)
Pacific Coast																
Los Angeles, CA	0.02	0.19	3.1	1.7	0.2	0.7	1.9	2	0.9	6.4	2.8	48	0.001	0.013	4.6	0.26
Alameda, CA	0.2	1.4	2.6	9.1	0.4	2.9	2.6	19	3.0	21	2.7	147	0.01	0.048	2.8	0.36
Coos, OR	0.4	2.0	2.2	9.4	1.0	4.0	2.0	16	4.0	22	2.4	122	0.01	0.081	4.1	1.3
Western States																
Navajo, AZ	0.3	2.8	2.9	23	4.9	21	2.1	169	20	120	2.5	723	0.09	0.48	2.4	2.7
Clark, NV	0.4	5.5	3.6	68	2.9	16	2.4	197	3.5	38	3.4	418	0.04	0.82	4.4	15
Washington, UT	2.5	23	3.1	211	9.2	51	2.4	468	13	210	4.1	3336	0.3	3.2	3.2	31
Mountain States																
Boise, ID	1.4	19	3.8	260	3.4	31	3.1	424	15	180	3.5	2097	0.05	1.5	5.8	47
Meagher, MT	2.5	43	4.3	750	3.8	55	3.9	959	20	330	4.2	5496	0.11	0.91	2.9	7.3
Denver, CO	4.2	12	1.7	34	11.5	29	1.6	82	34	120	1.9	422	0.04	0.52	3.5	6.1
Central States																
Scott, MN	2.7	15	2.4	83	4.5	23	2.3	128	18	120	2.6	781	0.11	0.61	2.4	3.4
Milwaukee, WI	2.2	8.4	2.0	33	2.8	13	2.2	51	20	79	2.0	307	0.08	0.31	2.0	1.2
St. Louis, MO	2.3	13	2.4	72	5.4	30	2.4	167	23	130	2.4	723	0.20	0.69	1.9	2.4
Franklin, KS	3.3	14	2.1	60	6.9	27	2.0	116	29	150	2.3	767	0.24	0.75	1.8	2.4
Southeast States																
Orange, FL	0.3	1.8	2.4	10	3.3	14	2.1	78	9.4	61	2.6	397	0.10	0.25	1.6	0.6
Anderson, TN	1.8	6.5	1.9	23	4.3	15	1.9	53	34	120	1.9	422	0.18	0.46	1.6	1.2
Washington, DC	1.2	5.0	2.1	21	1.2	5.0	2.1	21	13	70	2.4	389	0.02	0.20	3.5	2.3
Northeast States																
Albany, NY	1.1	9.7	3	84	2.2	23.0	3.3	198	12	100	2.9	806	0.05	0.43	2.9	3.5
Columbiana, OH	0.18	4.1	4.9	92	0.23	5.5	5.0	124	1.1	32	5.7	970	0.02	0.31	4.1	4.9
Hartford, CT	1.5	11	2.8	83	3.4	19	2.4	143	14	110	2.9	887	0.07	0.35	2.3	1.8
York, ME	1.5	7.7	2.3	39	3.3	13	2	67	13	75	2.4	417	0.10	0.31	1.8	1.0

The original NCI web site (http:www2.nci.nih.gov/fallout/html) gives only the geometric mean and the geometric standard deviaton. The 95% uncertainty range is calculated as 97.5%tile = GM*(GSD^1.96); 2.5%tile = GM/(GSD^1.96)

ATTACHMENT

2

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

DATE: December 19, 1997

TO: Dr. Richard Klausner, Director, NCI

FROM: Charles Land, Ph.D., Health Statistician, DCEG/EBP/REB
THROUGH: Director, DCEG __________

SUBJECT: Uncertainty of estimated thyroid cancer risk related to ^{131}I fallout from the Nevada Test Site: Correction of my memo of September 23, 1997, and some related developments.

In my memorandum of September 23, 1997, on "Calculation of lifetime thyroid cancer risk for an average thyroid dose of 0.02 Gy from I-131 in fallout," I presented the method used to calculate the estimates included in the press release of August 1. The range of estimates was from 7,500 to 75,000, reflecting assumed values from 0.1 to 1.0 for the relative biological effectiveness of thyroid dose from ^{131}I as compared to gamma ray and x ray in the induction of thyroid cancer. In my memo, I also included a short paragraph illustrating the consequences of statistical and subjective uncertainty about the excess relative risk coefficient (7.7 at 1 Gy) estimated by Ron et al. and about the average population thyroid dose (0.02 Gy) estimated in the NCI report. That paragraph, which was not included in the press release, is given below:

"The range of estimates does not take into account statistical uncertainty about the Ron coefficients or statistical and subjective uncertainty about the estimated average dose. The Ron estimate of ERR_{1Gy} = 7.7 had 95% confidence limits 2.1-28.7, corresponding to a geometric standard deviation (GSD) of about 1.95. The average dose estimated by the NCI, 2 rad, was assigned a GSD of 3, and therefore the product of that dose and the estimated ERR at 1 rad has a GSD of 3.6 (calculated as the exponential of the square root of the sum of squares of the natural logarithms of 1.95 and 3). Approximate 95% confidence limits for the number of excess cases are obtained by dividing and multiplying by 12.4 ($=3.6^{1.96}$). Thus, for example, ignoring all other possible sources of error, an estimate of 49,000 lifetime excess cases (corresponding to RBE=0.66) would have confidence limits 4,000-608,000."

In the above calculation, I used the wrong value for the GSD of the average dose estimate, i.e., 3 instead of 1.4. (An approximate 95% uncertainty range of 1 to 4 was given in the Executive Summary of the report for the average dose estimate of 2 rad. Thus, the lower and upper limits are factors of 2 lower and higher than the point estimate, corresponding to a GSD equal to the square root of 2 ($2^{1/1.96}$), or about 1.4.) I asked about "error," heard "3," and assumed it was the GSD. The corrected paragraph, beginning with the third sentence, now reads as follows:

"The average dose estimated by the NCI, 2 rad, was assigned a GSD of **1.4**, and therefore the product of that dose and the estimated ERR at 1 rad has a GSD of **2.1** (calculated as the exponential of the square root of the sum of squares of the natural logarithms of 1.95 and **1.4**). Approximate 95% confidence limits for the number of excess cases are obtained by dividing and multiplying by **4.3** (=**2.1**$^{1.96}$). Thus, for example, ignoring all other possible sources of error, an estimate of 49,000 lifetime excess cases (corresponding to RBE=0.66) would have confidence limits **11,300-212,000**."

The corrected range of uncertainty due to the risk coefficient and the dose estimate is only one-third as large as I originally estimated. A corrected version of my memo of September 23 is attached (Att. 1). Also attached (Att. 2) is material used in the overheads for my presentation to the first meeting of the NAS/IOM advisory committee on December 18, to which I have added some further material at the end in case I have to give the talk again.

Yours sincerely,

Charles Land

RH 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

DATE: December 18, 1997

TO: Dr. Richard Klausner, Director, NCI

FROM: Charles Land, Ph.D., Health Statistician, DCEG/EBP/REB
THROUGH: Director, DCEG _________

SUBJECT: Calculation of lifetime thyroid cancer risk for an average thyroid dose of 0.02 Gy from I-131 in fallout (corrected).

My calculations of the thyroid cancer risk that might be associated with exposure to the American public to ^{131}I fallout from the Nevada Test Site resulted in an estimated range of 7,500 to 75,000 excess thyroid cancers during the lifetimes of those exposed before 20 years of age. This range of estimates may be compared with about 400,000 expected, according to current SEER rates, among this segment of the US population. Thus, the estimated excess is between 2% and 19% of what might be expected in the absence of exposure. The calculations were based on a published, pooled analysis of thyroid cancer risk data from 5 cohort studies of populations exposed during childhood to medical x ray, or to gamma ray from the atomic bombings of Hiroshima and Nagasaki (Ron et al, 1995). They also incorporate various assumptions about the relative biological effectiveness (RBE) of ^{131}I compared to x ray or gamma ray. Significant excess risk was assumed to occur only following exposure before 20 years of age, in accordance with the epidemiological literature. A linear dose response was assumed, and the dose-specific excess relative risk, which was assumed to decrease sharply with increasing age at exposure, was also assumed to remain constant over the lifetime of the exposed population.

The calculations (see the attached Excel spreadsheet)

Column 1 identifies the exposure ages considered. The first year of life was treated separately and older ages were grouped: 1-4, 5-9, 10-14, and 15-19. Exposure at ages older than 20 was ignored because there is little or no evidence of an excess cancer risk associated with exposure in adult life even to gamma and x-ray radiation. Columns 2 and 3 give the estimated number of persons in the 1952 population of the US, by age and sex, as interpolated from 1950 and 1960 census numbers. The total number exposed at ages 0-19 also includes persons born in 1953, 1954, etc., but the entry into the population of newborn persons is largely compensated by the loss of persons reaching age 20 in the same years. With a linear dose-response model and lifetime excess risk, error introduced by acting as if the population 0-19 years of age in 1952 received all the dose that was actually received by those who were 0-19 years old during any part of the above-ground testing period is relatively unimportant.

Column 4 gives age-specific average thyroid doses in rad corresponding to the assumed average dose of 2 rad (0.02 Gy), based on information provided by Andre Bouville (this is why the first year of life was separated from the next four). As you know, thyroid doses to children are larger than those for adults because of smaller gland size, higher milk intake, and higher metabolism.

Column 5 gives age-specific, linear dose-response coefficients for x ray and gamma ray, derived from Ron et al (1995). Their overall coefficient for excess relative risk (ERR) at 1 rad was 0.077. They also did analyses suggesting that the ERR decreases by a factor of 2 for each successive 5-year interval of age at exposure, over the range 0-14 years of age. I derived the values in column 5 from the Ron et al analysis, and extended the 2-fold reduction rule to 15-19 years at exposure. In each subsection, the age-specific coefficients have been multiplied by the specified RBE value.

Columns 6 and 7 are the estimated lifetime excess thyroid cancer rates for males and females, computed by multiplying the product of columns 4 and 5 by 0.25% for males and 0.64% for females, respectively; these percentages are the SEER (1973-1992) report's estimated lifetime thyroid cancer rates for men and women. The 1973-94 SEER volume is now out, and gives 0.27% for males and 0.66% for females. Use of the new values would increase the total by about 4%.

Columns 8 and 9 were obtained by multiplying columns 2 and 3 by columns 6 and 7, respectively, and column 10 is the sum of columns 8 and 9. One implication of column 10 is that 75% of all the excess risk is estimated to result from exposure during the first 5 years of life.

The calculations are repeated for RBE values of 1.0, 0.66, 0.3, and 0.1.

Sources of uncertainty

NCRP report No.80, "Induction of Thyroid Cancer by Ionizing Radiation," 1985, gave a range of 0.1 to 1.0 for the RBE of thyroid dose from ingested or inhaled I-131 compared to gamma ray or x ray, based on experimental studies. The report recommended 0.3 for radiation protection purposes, as the highest credible value. The NCRP report also stated that the RBE of ^{131}I relative to x ray may be lower at high doses and dose rates, and higher (nearer to x ray in effectiveness) at low doses and dose rates. Thus, Walinder (1972, summarized in the NCRP report) obtained an RBE of 0.1 using ^{131}I thyroid doses in the range 2200-11,000 rad whereas Lee et al (1982) found near equivalence using dose groups at 80, 330, and 850 rad. Laird (1987) conducted parallel and combined analyses of 6 cohorts of children exposed to external radiation and one exposed to ^{131}I, and reevaluated experimental data from the large study by Lee et al (1982) specifically designed to investigate the RBE of ^{131}I. Her RBE estimate was 0.66 with 95% confidence limits 0.14-3.15 (however, there is no support that I know of for an RBE greater than 1). The RBE value at low doses remains a contentious issue.

The range of estimates does not take into account statistical uncertainty about the Ron coefficients or statistical and subjective uncertainty about the estimated average dose. The Ron estimate of $ERR_{1Gy} = 7.7$ had 95% confidence limits 2.1-28.7, corresponding to a geometric standard deviation (GSD) of about 1.95. The average dose estimated by the NCI, 2 rad, was assigned a GSD of 1.4, and therefore the product of that dose and the estimated ERR at 1 rad has a GSD of 2.1 (calculated as the exponential of the square root of the sum of squares of the natural logarithms of 1.95 and 1.4). Approximate 95% confidence limits for the number of excess cases are obtained by dividing and multiplying by 4.3 ($=2.1^{1.96}$). Thus, for example, ignoring all other possible sources of error, an estimate of 49,000 lifetime excess cases (corresponding to RBE=0.66) would have confidence limits 11,300-212,000.

According to the model used for the estimates, ERR is constant over time following exposure, and about one third of the total excess lifetime risk among men in the exposed population, and about half among women, should already have taken place. It is possible, however, that the actual excess relative risk per unit dose may decline over time following exposure, most of which occurred over 40 years ago. Ron et al found significant variation by time following exposure, but did not find a statistically significant trend. At the present time there are few data on radiation-related thyroid cancer risk 40 or more years following exposure during childhood, and therefore little basis for a discussion of the question.

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1	2	3	4	5	6	7	8	9	10
Age at exp.	1952 population		Estimated average thyroid dose (rad)	ERR at 1 rad (Ron et al, 1995)	Excess rate (lifetime)		# lifetime excess thyroid cancers		
	Males	Females			Males	Females	Males	Females	Total
				1. RBE = 1					
0	1,757,800	1,698,600	10.3	0.098	0.002524	0.00646	4,435.8	10,973.2	15,409.0
1-4	7,171,000	6,931,200	6.7	0.098	0.001642	0.004202	11,771.2	29,126.6	40,897.8
5-9	7,174,043	6,929,430	4.5	0.049	0.000551	0.001411	3,954.7	9,778.8	13,733.5
10-14	6,236,357	6,023,970	2.8	0.0245	0.000172	0.000439	1,069.5	2,644.8	3,714.3
15-19	5,916,664	5,715,114	1.8	0.01225	5.51E-05	0.000141	326.2	806.5	1,132.7
Total	28,255,864	27,298,314					21,557	53,330	74,887
				2. RBE = 0.66					
0	1,757,800	1,698,600	10.3	0.06468	0.001666	0.004264	2,927.6	7,242.3	10,170.0
1-4	7,171,000	6,931,200	6.7	0.06468	0.001083	0.002773	7,769.0	19,223.5	26,992.5
5-9	7,174,043	6,929,430	4.5	0.03234	0.000364	0.000931	2,610.1	6,454.0	9,064.1
10-14	6,236,357	6,023,970	2.8	0.01617	0.000113	0.00029	705.9	1,745.5	2,451.4
15-19	5,916,664	5,715,114	1.8	0.008085	3.64E-05	9.31E-05	215.3	532.3	747.6
Total	28,255,864	27,298,314					14,228	35,198	49,426
				3. RBE = 0.3					
0	1,757,800	1,698,600	10.3	0.0294	0.000757	0.001938	1,330.7	3,292.0	4,622.7
1-4	7,171,000	6,931,200	6.7	0.0294	0.000492	0.001261	3,531.4	8,738.0	12,269.3
5-9	7,174,043	6,929,430	4.5	0.0147	0.000165	0.000423	1,186.4	2,933.6	4,120.1
10-14	6,236,357	6,023,970	2.8	0.00735	5.15E-05	0.000132	320.9	793.4	1,114.3
15-19	5,916,664	5,715,114	1.8	0.003675	1.65E-05	4.23E-05	97.8	242.0	339.8
Total	28,255,864	27,298,314					6,467	15,999	22,466
				4. RBE=0.1					
0	1,757,800	1,698,600	10.3	0.0098	0.000252	0.000646	443.6	1,097.3	1,540.9
1-4	7,171,000	6,931,200	6.7	0.0098	0.000164	0.00042	1,177.1	2,912.7	4,089.8
5-9	7,174,043	6,929,430	4.5	0.0049	5.51E-05	0.000141	395.5	977.9	1,373.4
10-14	6,236,357	6,023,970	2.8	0.00245	1.72E-05	4.39E-05	107.0	264.5	371.4
15-19	5,916,664	5,715,114	1.8	0.001225	5.51E-06	1.41E-05	32.6	80.7	113.3
Total	28,255,864	27,298,314					2,156	5,333	7,489

R# 2.

Calculation of the Estimated Lifetime Risk of Radiation-Related Thyroid Cancer in the U.S. Population from NTS Fallout

Charles Land

(Presented at the NAS/IOM advisory committee meeting, 12/18/97)

1. Thyroid cancer risk associated with gamma-ray and x-ray exposure, from studies of the Hiroshima-Nagasaki survivors and of various medically-exposed populations, is well quantified. Findings are summarized in a pooled analysis of seven studies (Ron et al, Radiation Research 1995; 141:259-277).

- The evidence for a radiation-related risk is strong for childhood exposure, and weak or non-existent for adult exposure.
- Dose-specific excess risk decreases with increasing age at exposure. At ages 5-9, it is about half that associated with exposure at ages 0-4, and at 10-14 it is about half that at 5-9.
- For any given exposure age, excess risk appears to be proportional to thyroid dose (linear dose response).
- Ron et al. estimated an excess relative risk (ERR) of 7.7 per Gy, or 0.077 per rad, for childhood exposure at ages younger than 15.

2. The average (case-weighted) exposure age in the pooled data was a little over 4 ½ years. By linear interpolation between the midpoints of the first two intervals, and extension of the observed reduction in ERR with increasing age at exposure, the following age-specific coefficients were inferred:

Age at exposure	ERR at 1 rad
0-4	0.098
5-9	0.049
10-14	0.0245
15-19	0.01225
≥20	negligible

3. Although there was evidence of variation in radiation-related relative risk over time following exposure, there was no evidence of a trend. Accordingly, ERR was assumed to remain constant over the remainder of life.

4. Data on risk associated with thyroid exposure from ingested or inhaled ^{131}I suggest that there is a risk, but precise dose-response estimates are not available. Accordingly, it is reasonable to use the coefficients developed from data on x-ray and gamma-ray exposure , with an appropriate value for the relative biological effectiveness of ^{131}I compared to gamma rays or x rays.

- NCRP report No.80, "Induction of Thyroid Cancer by Ionizing Radiation," 1985, gave a range of 0.1 to 1.0 for the RBE, based on experimental studies. The report recommended 0.3 for radiation protection purposes, as the highest credible value. The NCRP report also stated that the RBE of ^{131}I relative to x ray may be lower at high doses and dose rates, and higher (nearer to x ray in effectiveness) at low doses and dose rates.

- Thus, Walinder (1972, summarized in the NCRP report) obtained an RBE of 0.1 using ^{131}I thyroid doses in the range 2200-11,000 rad, whereas

- Lee et al (1982) found near equivalence using dose groups at 80, 330, and 850 rad.

- Laird (1987) conducted parallel and combined analyses of 6 cohorts of children exposed to external radiation and one exposed to ^{131}I, and reevaluated experimental data from the large study by Lee et al (1982) specifically designed to investigate the RBE of ^{131}I. Her RBE estimate was 0.66 with 95% confidence limits 0.14-3.15 (however, there is little or no support for an RBE greater than 1).

- The RBE value at low doses remains a contentious issue.

- In the calculations for NCI, RBE values of 1, 0.66, 0.33, and 0.1 were assumed.

5. In addition to being more sensitive to the carcinogenic effects of ionizing radiation, the thyroid glands of children receive higher doses from ingested or inhaled ^{131}I than do the glands of adults, because of smaller gland size, higher intake of milk, and higher metabolism. Using conversion factors obtained from Dr. Bouville, the estimated average thyroid dose of 2 rad to the U.S. population from Nevada Test Site fallout was converted to the following values for children:

Exposure Age	Estimated Average Dose
<1	10.3
1-4	6.7
5-9	4.5
10-14	2.8
15-19	1.8

6. Lifetime cumulative thyroid cancer incidence rates of 0.25% for males and 0.64% for females, respectively, were assumed, based on the SEER report for 1973-1992. The 1973-94 SEER volume is now out, and gives 0.27% for males and 0.66% for females. Use of the new values would increase the total by about 4%.

7. For simplicity of calculation, it was assumed that the U.S. population in 1952 received the total thyroid dose from NTS fallout in that year, instead of spread out over 12 years. This simplification was possible because, using a linear dose-response model, lifetime radiation-related thyroid cancer risk is proportional to summed collective dose, in person-rads, over exposure ages weighted by age-specific risk coefficient.

8. For each single year of age (column 1 in the spreadsheet), the sex-specific estimated numbers of lifetime excess thyroid cancer cases in the US due to NTS fallout (cols 8 and 9) were obtained as the product of:

- the number of male or female persons in the 1952 US population (columns 2 and 3)
- the age-specific estimated average cumulative thyroid dose over

the entire period of above-ground testing (column 4)

- the age-specific linear dose-response coefficient (ERR at 1 rad) for x ray and gamma ray (column 5), times the assumed RBE for ^{131}I
- the cumulative lifetime thyroid cancer risk for men or women (0.25% or 0.64%), as appropriate.

9. The age and sex-specific totals were summed over sexes (col 10)and ages. The sums are given below columns 8-10 in each table.

10. Besides uncertainty about the RBE, there is also statistical uncertainty about the risk coefficients, and subjective and statistical uncertainty about the average doses used. The combined uncertainty is substantial. For example:

- 95% confidence limits (2.1-28.7) for the Ron estimate of ERR_{1Gy} = 7.7 correspond approximately to a lognormal model geometric standard deviation (GSD) of about 1.95.
- The uncertainty of average dose estimated by the NCI, 2 rad, was stated to be between 1 and 4, i.e., a factor of 2 in each direction. This corresponds approximately to 95% confidence limits and thus to a GSD of about 1.4.
- Therefore, the product of that dose and the estimated ERR at 1 rad has a GSD of 2.1 (calculated as the exponential of the square root of the sum of squares of the natural logarithms of 1.95 and 1.4).
- Approximate 95% confidence limits for the number of excess cases can be obtained by dividing and multiplying by 4.3 ($=2.1^{1.96}$). Thus, for example, ignoring all other possible sources of error, an estimate of 49,000 lifetime excess cases (corresponding to a fixed RBE of 0.66, which here is assumed to be known without error) might be given with uncertainty 11,300-212,000.

Some supplementary notes:

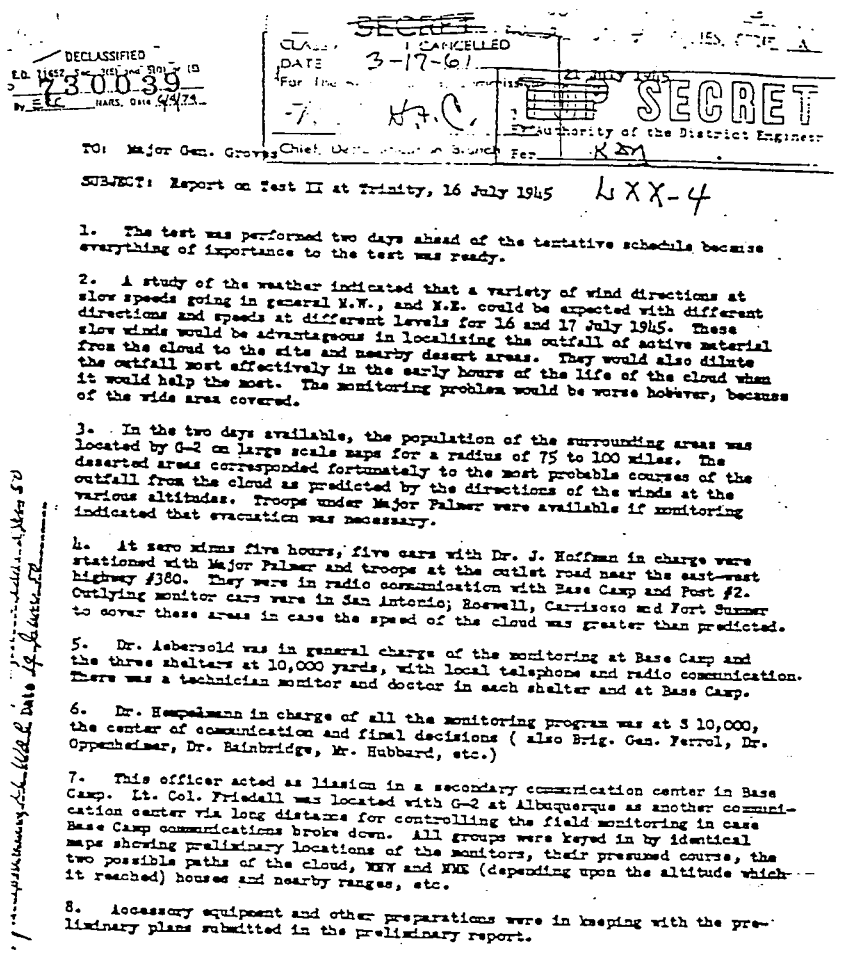
1. Continuing with the above example, the following 95% uncertainty intervals would be obtained for other RBE value assumptions:

Assumed RBE	Central estimate	95% uncertainty interval
1.0	75,000	17,000-324,000
0.66	49,000	11,300-212,000
0.3	22,000	5,100-95,000
0.1	7,500	1,700-32,000

2. At the December 18-19 meeting of the National Academy of Sciences /Institute of Medicine committee formed to advise the NCI on the public health implications of the NCI dose and risk estimates, Dr. Owen Hoffman, at the committee's invitation, presented the results of a Monte Carlo simulation analysis in which the RBE could be 1.0, 0.66, 0.5, 0.33, or 0.2, with probabilities 35%, 40%, 15%, 7%, and 3%, respectively. Taking into account this additional degree of uncertainty, he obtained a central estimate of 46,000 with 95% uncertainty limits 8,000-208,000.

ATTACHMENT

3



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By ETC NARS, Date 6/4/74

~~SECRET~~
CLASS. CANCELLED
DATE 3-17-61
For The [illegible] Commission
Chief, Declassification Branch

21 July 1945

SECRET
By Authority of the District Engineer
Per KDM

TO: Major Gen. Groves

SUBJECT: Report on Test II at Trinity, 16 July 1945

LXX-4

1. The test was performed two days ahead of the tentative schedule because everything of importance to the test was ready.

2. A study of the weather indicated that a variety of wind directions at slow speeds going in general N.W., and N.E. could be expected with different directions and speeds at different levels for 16 and 17 July 1945. These slow winds would be advantageous in localizing the outfall of active material from the cloud to the site and nearby desert areas. They would also dilute the outfall most effectively in the early hours of the life of the cloud when it would help the most. The monitoring problem would be worse however, because of the wide area covered.

3. In the two days available, the population of the surrounding areas was located by G-2 on large scale maps for a radius of 75 to 100 miles. The deserted areas corresponded fortunately to the most probable courses of the outfall from the cloud as predicted by the directions of the winds at the various altitudes. Troops under Major Palmer were available if monitoring indicated that evacuation was necessary.

4. At zero minus five hours, five cars with Dr. J. Hoffman in charge were stationed with Major Palmer and troops at the outlet road near the east-west highway #380. They were in radio communication with Base Camp and Post #2. Outlying monitor cars were in San Antonio; Roswell, Carrizozo and Fort Sumner to cover these areas in case the speed of the cloud was greater than predicted.

5. Dr. Aebersold was in general charge of the monitoring at Base Camp and the three shelters at 10,000 yards, with local telephone and radio communication. There was a technician monitor and doctor in each shelter and at Base Camp.

6. Dr. Hempelmann in charge of all the monitoring program was at S 10,000, the center of communication and final decisions (also Brig. Gen. Farrel, Dr. Oppenheimer, Dr. Bainbridge, Mr. Hubbard, etc.)

7. This officer acted as liasion in a secondary communication center in Base Camp. Lt. Col. Friedall was located with G-2 at Albuquerque as another communication center via long distance for controlling the field monitoring in case Base Camp communications broke down. All groups were keyed in by identical maps showing preliminary locations of the monitors, their presumed course, the two possible paths of the cloud, NNW and NNE (depending upon the altitude which it reached) houses and nearby ranges, etc.

8. Accessory equipment and other preparations were in keeping with the preliminary plans submitted in the preliminary report.

~~SECRET~~

21 July 1945

9. The shot was fired at 0530 on 16 July 1945.
The energy developed in the test was several times greater than that expected by scientific group. The cloud column mass and top reached a phenomenal height, variously estimated as 50,000 to 70,000 feet. It remained towering over the northeast corner of the site for several hours. This was sufficient time for the majority of the largest particles to fall out. Various levels were seen to move in different directions. In general the lower one-third drifted eastward, the middle portion to the West and northwest, while the upper third moved northeast. Many small sheets of dust moved independently at all levels and large sheets remained practically in situ. By zero plus 2 hours, the main masses were no longer identifiable except for the very high white mass presumably in the stratosphere.

10. By 0800 hours the monitors reported an area of high intensity in a canyon 20 miles northeast of zero. Since this was beyond the tolerance set and equally high intensities were expected in other areas, four more monitor cars were sent into this northeast area from Base Camp. The roving monitors in this area were each accompanied by a trooper in a 4 wheel drive and authorized to evacuate families if necessary. At no house in this whole north and northeast area between 20 miles and 40 miles from zero was a dangerous intensity found. The highest intensities fortunately, were only found in deserted regions. The highest found is shown in detail attached #1. Intensities in the deserted canyon were high enough to cause serious physiological effects.

11. The distribution over the countryside was spotty and subject to local winds and contour. It skipped the nearby highway #380 (20mi. N.E.) except for low intensities which were equaled at twice and three times the distances. It is presumed that the largest outfall occurred in the N.E. quadrant of the site. This can only be explored by horseback at a later date.

12. The monitors all took considerable risks knowingly and many have received exposures of considerable amounts, i.e., 8r total. This is safe within a considerable margin. They should not be exposed to more radiation within the next month.

13. The dust could be measured at low intensities 200 miles north and northeast of the site on the 4th day. (Attached #2) There is still a tremendous quantity of radioactive dust floating in the air.

14. Neither the Base Camp or the shelters were contaminated very much.

15. Partially evicerated dead wild jack rabbits were found more than 800 yards from zero, presumably killed by the blast. A farm house 3 miles away had doors torn loose and suffered other extensive damage.

16. Details indicating blast, heat and other effects cannot be worked out until the area around the crater "cools down".

It is this officer's opinion, however, that lethal or severe casualities would occur in exposed personnel up to two miles from a variety or combination of causes, ie., blast, heat, ultraviolet and missles.

21 July 1945

The light intensity was sufficient at nine miles to have caused temporary blindness and this would be longer lasting at shorter distances. Several observers at 20 miles were bothered by a large blind spot for-15 minutes after the shot. The light together with the heat and ultraviolet radiation would probably cause severe damage to the unprotected eyes at 5-6 miles; damage sufficient to put personnel out of action several days if not permanently. All of the personnel obeyed the safety precautions during the test so that no such injury resulted.

17. A great deal of experience was obtained on the requirements for quick and adequate monitoring. Excellent radio communications, good transportation and better and more rugged meters are required.

18. It is this officer's opinion based on the damage to "Jumbo" (2400 ft), the extent of the glazed sand area (up to 500 ft.), the extent of the cleaned off area (about 1 mile), the farm house (at 3 miles) that this explosion was a great many times more violent than the 100 ton test. "Conservative" estimates by the scientific groups put it at least equivalent to 10,000 tons of T.N.T.

19. While no house area investigated received a dangerous amount, ie., no more than an accumulated two weeks dosage of 60r, the dust outfall from the various portions of the cloud was potentially a very dangerous hazard over a band almost 30 miles wide extending almost 90 miles northeast of the site.

20. It is this officer's opinion that this site is too small for a repetition of a similar test of this magnitude except under very special conditions. It is recommended that the site be expanded or a larger one, preferably with a radius of at least 150 miles without population, be obtained if this test is to be repeated.

Colonel Stafford L. Warren
Chief of Medical Section
Manhattan District

SLW/fp

cc/ Maj. Gen Groves (2)
R. Oppenheimer (1)
Col. Warren (1)

ATTACHMENT

4

Worse than we knew

By Pat Ortmeyer & Arjun Makhijani

Fallout exposed nearly everyone in the United States to radioactive iodine. And the government knew it.

On August 1, the National Cancer Institute (NCI) revealed that as a result of U.S. nuclear tests conducted in the atmosphere in Nevada, American children were actually exposed to 15 to 70 times as much radiation as had been previously reported to Congress. As a result, many thousands of today's adults are at risk of developing thyroid cancer.

This information comes from fragments of a congressionally mandated study, 14 years in the making. The NCI report details estimated radiation doses to the thyroid gland due to releases of radioactive iodine 131. Most of the releases occurred from 1951 to 1958.

Although areas near the Nevada Test Site were most often contaminated, the newly released data show that virtually the entire continental United States was affected and "hot spots" occurred in unpredictable places far from the site. These hot spots occurred because rainstorms sometimes caused locally heavy deposits of fallout. As a result, some children in large portions of the Midwest, parts of New England, and areas east and northeast of the test site (Idaho, Montana, and the Dakotas) received doses of iodine 131 as high as 112 rads.

These dose estimates refer not to whole-body exposure, but to the concentration of iodine 131 in the thyroid gland, which occurred primarily through the "milk pathway." As cows and goats grazed in fallout-contaminated pastures, iodine 131 contaminated their milk. Children received high thyroid doses because they drank much more milk than adults, they had smaller thyroids, and their thyroids were growing. In making its county-by-county estimates, NCI used both milk production and consumption patterns as well as weather data.

What the government knew

Given the location of the U.S. test site, none of the NCI's findings should come as a surprise to the nuclear weapons establishment, which knew from the beginning that a western test site would spread contamination across most of the country. In 1948, for instance, the committee assigned to choosing a location was told by U.S. Air Force Meteorologist Col. B. G. Holzman that an East Coast site would be advisable "because the United States is predominantly under the influence of westerly winds."[1]

Instead, the committee chose a western site because the weapons labs were nearby, which it felt would be helpful in "accelerating the pace of the weapons development program."[2]

Estimates of thyroid doses, first reported in testimony to Congress in 1959—and still cited in 1997—ranged from 0.2 to 0.4 rad. (According to the NCI, 0.4 rad is roughly the radiation dose delivered by one mammogram.) But American children on average actually received an estimated cumulative dose to the thyroid of 6 to 14 rads, and in the 24 most heavily contaminated counties, doses were between 27 and 112 rads.

The exposure of millions of children is especially troubling because much of it could have been avoided. The Atomic Energy Commission (AEC) learned about the risks of fallout and the prevalence of hot spots with the first atomic test, and the AEC was aware of the danger of

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consuming contaminated milk during most of the years of testing in Nevada.

Early warning

Authorities had an early tangible warning that fallout from nuclear tests would travel far from the site of a detonation and that care would be needed to contain it. Fallout was discovered 200 miles from the test site where "Trinity," the first nuclear bomb, was detonated in New Mexico in July 1945. As a result, Stafford Warren, the Manhattan Project's chief of radiological safety, recommended to Gen. Leslie Groves, head of the project, that future tests should be conducted at least 150 miles away from civilian populations.[3]

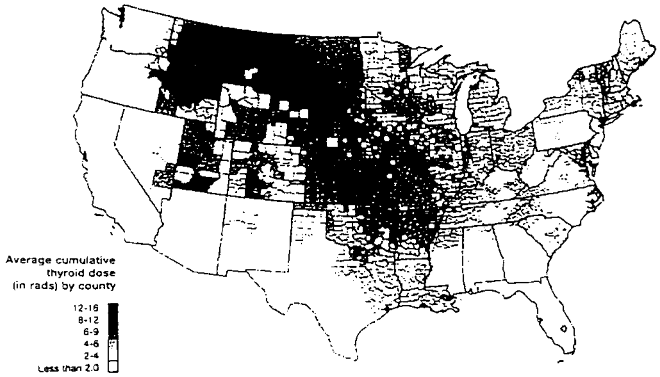
The Trinity test also resulted in at least one hot spot in Indiana, over 1,000 miles away. A month after the test, customers of the Eastman Kodak Company began complaining about buying fogged X-ray film. After investigating, an Eastman Kodak physicist determined that packing material—made from corn husks at a plant in Indiana—had been radioactively contaminated. The physicist also deduced that the origin of the contamination was an atomic explosion. His knowledge of the secret project was not altogether surprising: the Kodak Company ran the Tennessee Eastman uranium processing plant at the Oak Ridge National Laboratory.

Kodak also reported problems from fallout after the first test in Nevada in January 1951, but this time they occurred as far away as company headquarters in Rochester, New York. After a snowstorm, Geiger counters at the Kodak plant showed readings 25 times above normal. When Kodak complained and threatened to sue, the Atomic Energy Commission agreed to give the company "advance information on future tests" including "expected distribution of radioactive material in order to anticipate local contamination."[4]

In fact, the entire photographic film industry was warned about fallout. Throughout the atmospheric testing program, AEC officials gave the photographic industry maps and forecasts of potential contamination, as well as expected fallout distributions, which enabled them to purchase uncontaminated materials and take other protective measures. The National Association of Photographic Manufacturers was also given some data on the nature of the test shots "for their own information."

But the AEC did not see fit to provide milk producers or consumers with similar information, even when the significance of the milk pathway became clear.

One of the better known hot spots occurred in Albany, New York, after the "Simon" test in April 1953. After a heavy rainstorm, students in a college radiochemistry class noticed that their



Source: National Cancer Institute

By 1955, non-AEC reports were detailing the high doses of iodine 131 in cows' milk. But AEC researchers like these were more circumspect.

Geiger counters showed readings as high as 1,000 times above normal. Measurements taken from roofs, puddles, buildings, and foliage around town showed equally elevated readings. In a 1954 report, the AEC described this incident as "an interesting example of a small area of very intense fallout."

But the AEC report that evaluated the Albany incident also indicated that fallout as far as 600 miles from the test site, in areas such as western Kansas, could deposit 1,000 to 100,000 times the radioactivity recorded in Albany. The report also recommended that, since hot spots were more likely to occur during months with the greatest precipitation, "Total fallout in the United States could be reduced somewhat by scheduling test series in the late fall," when storms were least likely to occur.

This recommendation was largely ignored.

Deceit and denial

Although public concern about fallout grew in the early 1950s, the AEC consistently denied that the public was in danger. But the AEC's collection of milk samples was haphazard at best. For example, in 1953, the Public Health Service was asked to obtain milk samples in St. George, Utah, near the test site. But the service took a sample from a carton of milk purchased in a store, not from a local farm or dairy—at a time when the majority of residents of southwest Utah obtained milk from their own cows and many others purchased milk from neighboring farms.

According to Morgan S. Seal, a fallout monitor with the Public Health Service, the testing procedure was not very useful either: "In the case of milk, we even treated it with perchloric acid to get rid of all the organic residue. . . . We knew for a fact then that those oxidating techniques completely eliminated any iodine in the material that you were treating."

Studies on animals exposed to iodine 131 had been going on since the 1940s, although they primarily involved direct measurement of the thyroid to detect iodine uptake rather than whether the radioactive iodine would contaminate the animal's milk.

In 1953, however, researchers at the Hanford Nuclear Reservation studied milk samples from sheep that had been fed iodine 131 pellets and concluded that similar iodine levels in bovine milk "suggest that [iodine 131] would be found in such dairy products as skim milk, cottage cheese, and whey."

In 1954, the *Journal of Dairy Research* was more direct in discussing the risk to humans of iodine in milk, indicating that "cows grazing in the neighborhood [near a nuclear power plant accident] may ingest sufficient of the isotope to constitute a danger to the consumers of their milk." Also in 1954, AEC-funded research determined that the elevated levels of iodine found in animal thyroids in Tennessee were linked to fallout from nuclear tests.[10]

Additional evidence of the danger of the milk pathway was presented by delegates to the U.N. Conference on Peaceful Uses of Atomic Energy in 1955. One research paper argued that radioactive iodine deposited in grazing areas became so highly concentrated in milk that the then-permissible levels of iodine 131 in the air were ten thousand times too high. "This limit should be reduced by four orders of magnitude to assure radiation safety for grazing animals. Approximately the same reduction is required for the safety of humans eating large quantities of fresh garden produce and drinking milk from cows grazing on iodine 131-contaminated pasture."[11] An Oxford University delegation to the conference stressed that "human beings whose diet consists largely of milk, notably infants . . . because of their youth may be considered super-susceptible to the effects of radiation."[12]

Although the Atomic Energy Commission ignored these recommendations, elsewhere attitudes were changing. In 1957, when a fire at Britain's Windscale reprocessing plant caused the release of between 16,200 and 27,000 curies of radioiodine, officials ordered all milk produced within a 200-square-mile area around the plant to be dumped as a precautionary measure. By comparison, cumulative releases of iodine 131 from atmospheric tests during the 1950s were around 150 million curies, but at no time did the government order that milk be dumped.

In 1959, in response to public concerns about fallout, President Dwight D. Eisenhower created the Federal Radiation Council and charged it with setting federal radiation standards. When it was discovered that iodine levels in milk in Utah exceeded its standards—and that fallout standards were being exceeded in hot spots around the country—state officials in Utah and Minnesota decided to divert contaminated milk from the market. But in 1962, the radiation council (whose members included the chairman of the AEC and the Secretary of Defense) made the remarkable determination that the radiation guidelines should not be applied to fallout without further detailed studies because "any possible health risk which may be associated with exposures even many times above the guide levels would not result in a detectable increase in the incidence of disease." The council also concluded that preventive measures, presumably such as diverting milk, may actually "have a net adverse rather than favorable effect on the public well-being."[13] In testimony before Congress in 1969, council chairman Paul C. Tompkins defended the failure to divert milk from the market by claiming that doing so would have caused malnutrition.[14]

In 1962 the AEC's Fallout Studies Branch produced a report indicating that after the "Harry" test in 1953, children living in St. George, Utah may have received doses to the thyroid of radioiodine as high as 120 to 440 rads. The AEC tried to suppress the report, but it was eventually released. However, a committee review appended to the report warned that its "specific conclusions must be regarded with considerable reservation."

The evidence of high thyroid doses from contaminated milk continued to grow. In 1966, another AEC study showed that children both directly downwind and far away from the test site had received high thyroid doses of iodine 131 from drinking contaminated milk. The highest thyroid doses were to children directly downwind: infants in St. George, Utah were estimated to have received 120 rads. But across the country, researchers found significant doses to children from iodine fallout: 46 rads in Salt Lake City, Utah; 56 rads in Roswell, New Mexico; 51 rads in Grand Junction, Colorado; 19 rads in Amarillo, Texas; and 15 rads in Albany, New York.[15]

Fallout from fallout

The National Cancer Institute study, only small portions of which were released in August, did not directly assess the risk of cancer as it relates to fallout. But researchers did predict that some 10,000 to 75,000 excess thyroid cancers could be expected from the reported doses, and that only 30 percent of those cancers had been diagnosed to date. In 1977 the NCI reported that the incidence of thyroid cancer was on the rise: in a 1969–71 survey there were 3.9 cases of thyroid cancer per 100,000 people, up from 2.4 cases per 100,000 in 1947—an increase of 62 percent. For Caucasians between the ages of 20 and 35 the rate doubled.

However, concluding that cases of thyroid cancer are a result of exposure to iodine 131 is not straightforward: during the years of atmospheric testing it was also common for physicians to treat an assortment of disorders with X-rays and other radiation sources. For example, from the 1940s to the 1960s, nasal applicators containing sealed radium 226 sources were used to treat nasal and inner ear problems and to reduce swelling of lymphoid tissue.

The National Cancer Institute estimates that around 160 million people—virtually everyone

The National Cancer Institute argues that more research is needed. But wouldn't screening be more useful?

living in the United States at the time—received some iodine dose from fallout. But those most at risk, according to a peer-reviewed 1995 study, are people who were exposed while under 15 years of age and who received a radiation dose of 10 rads or more. The risk is greatest for those exposed before the age of five.[15]

More specific numbers have not been released, but simple demographics coupled with the published numbers indicate that millions of people who were then under 15 may have been exposed to 10 rads or more. (About five to 10 percent of thyroid cancers are fatal; survivors require lifelong treatment with a synthetic thyroid hormone essential for metabolism and other physiological functions.)

What should be done?

The National Cancer Institute, which has been working on its study for nearly 14 years, argues that more research is needed. But the need to address uncertainties should not be an excuse for further delay—the government has a responsibility to the 160 million people who were unknowingly exposed. The complete report and the follow-up studies conducted by the National Academy of Sciences' Institute of Medicine should be released promptly so that those at risk can be notified and given appropriate medical screening.

In its study of populations exposed to iodine 131 releases at Hanford, the Agency for Toxic Substances and Disease Registry recommended screening all those who had received doses of 10 rads or more. Average doses to children in the 24 most affected counties in the NCI study were far greater (27 to 112 rads).

The thyroid survey in the Marshall Islands also offers a precedent: although contamination levels varied widely and no dose reconstruction was carried out, every Marshallese born before 1965 was eventually offered a free clinical examination.

These precedents, at Hanford and in the Marshall Islands, offer a foundation upon which a public policy response to thyroid doses from iodine fallout could be based.

The NCI claims that it did not release dose data four years ago when the preliminary results were known because the report was not yet complete. However, public health officials should have been informed, given the high dose estimates for many counties across the country. If estimated doses were revised downward in the final version, then no harm would have been done. Since thyroid cancer is highly treatable, screening could have been instituted earlier, possibly saving lives.

The failure to provide adequate warning of the dangers of fallout should not be compounded by a failure to release full information to the millions affected by iodine 131 fallout from atmospheric nuclear testing. ■

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2. Gordon E. Dean (Chairman, U.S. Atomic Energy Commission), "Location of Proving Ground for Atomic Weapons—Selection of a Continental Atomic Test Site," report by the Director of Military Application, U.S. AEC Document 141/7, Dec. 13, 1950, p. 5.

3. Col. Stafford L. Warren, memorandum to Maj. Gen. Leslie Groves, "Report on Test II at Trinity," July 16, 1945.

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5. Herbert M. Clark, "The Occurrence of an Unusually High-Level Radioactive Rainout in the Area of Troy, N.Y.," Science, vol. 119, May 7, 1954, p. 621.

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13. Federal Radiation Council press release, "Federal Radiation Council Position on Current Fallout Levels," Sept. 17, 1967, p. 3.

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ATTACHMENT

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ATOMIC ENERGY COMMISSION

SUMMARY OF RELATIONS BETWEEN THE AEC AND THE PHOTOGRAPHIC INDUSTRY REGARDING RADIOACTIVE CONTAMINATION FROM ATOMIC WEAPON TESTS, FROM JANUARY THROUGH DECEMBER 1951

Note by the Secretary

The attached report by the Director of Military Application [redacted] for the information of the Commission.

ROY B. SNAPP
Secretary

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For The U. S. Atomic Energy Commission
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ATOMIC ENERGY COMMISSION

SUMMARY OF RELATIONS BETWEEN THE AEC AND THE PHOTOGRAPHIC INDUSTRY REGARDING RADIOACTIVE CONTAMINATION FROM ATOMIC WEAPON TESTS, FROM JANUARY THROUGH DECEMBER 1951

Report by the Director of Military Application

INTRODUCTION

1. Dr. A. K. Chapman, General Manager of Eastman Kodak Company, reported to Mr. W. E. Kelley, Manager of New York Operations of the AEC, on November 5, 1951, that measurements of snow, air and water at Rochester, New York, showed a level of radioactivity that was 500 times the highest previously experienced following atomic bomb tests. As a result, the Eastman Kodak Company suspended several of their operations. When Mr. Kelley passed this information on to the Division of Military Application, he was asked to have his representatives make a personal check with the Eastman Kodak Company to determine and report the details of what had happened. This report is attached as Appendix "G".

2. Inasmuch as the President of Eastman Kodak had indicated on March 12, 1951, that his company might have to file claims for redress against the Government if substantial expenditures or considerable damage to photographic products resulted from atomic weapon tests, it is possible that the suspension of

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operations mentioned above may result in claims being asserted against the Government. This summary is therefore presented in order to trace the relations between the AEC and the photographic industry since January 1951, when the problem arose.

CONTAMINATION FROM RANGER

3. On January 29, 1951, Mr. William C. Babbitt, Managing Director of the National Association of Photographic Manufacturers,* telegraphed Dr. Smyth his fears that the atomic weapon tests in Nevada might produce radioactive contamination of photographic raw materials similar to that which occurred after the Alamogordo test and asked assistance of the Atomic Energy Commission (text of telegram in Appendix "A"). As a result of the Alamogordo test in New Mexico in 1945, there was radioactive contamination of paper stiffener board, which is packed with film to keep it from bending and which was being made at that time for the Eastman Kodak Company by a mill in Indiana on the Wabash River. The Chairman of the Atomic Energy Commission wired Mr. Babbitt back on January 30 (Appendix "A") to the effect that test planning included attention to this problem, the Manager of Santa Fe Operations had been informed, and that we would furnish such information as would be useful on any contaminated areas that developed. When contamination did appear in the snowfall in upper New York State late in January, the New York Operations Office was requested by the Division of Military Application to investigate and to give assistance to

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*The [redacted]l Association of Photographic Manufacturers is a [redacted]ciation which, according to a Department of Commerce publication dated 1949, was established in 1946, has a paid staff of three to five persons, and has 80 to 90 members who are manufacturers of photographic equipment.

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the photographic industry. On February 2, the New York Operations Office issued the press release given in Appendix "B".

4. Dr. Julian H. Webb of the Research Laboratory of the Eastman Kodak Company, who had an active "Q" clearance, was invited to a meeting arranged by the Division of Military Application in Washington on February 13, to discuss the situation. Also present were personnel from the Air Force, Naval Research Laboratory, the AEC Divisions of Research, Biology and Medicine, and Military Application, and the New York Operations Office. Information concerning the detection of radioactive contamination and its removal by air and water filtration was made available to Dr. Webb. It appeared that the filtration systems already in use in photographic emulsion plants would afford considerable protection. However, mills making photographic paper did not normally take such stringent precautions and, in two cases at least, appreciable contamination at such mills had been detected. (See summary by Dr. English in Appendix "C".) Dr. Webb talked with Dr. Smyth and Mr. Pike following the meeting. On the same day, mention was made in a Commission meeting of the concern of the photographic industry in regard to future tests. The General Manager informed the Division of Military Application that the Commissioners saw no serious objection to giving responsible people in the industry an approximate idea of the date of future tests in order to help them with their problem. Mr. Pike was in Rochester, New York, on February 16 and discussed the contamination problem with officials of the Eastman Kodak Company.

5. Dr. Webb was designated by the National Association of Photographic Manufacturers as its representative on these matters and came to Washington for another meeting on March 6. He was

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given a copy of a report of February 27 from the New York Operations Office on "Survey of Fall-Out of Radioactive Material Following the Las Vegas, Nevada, Test Explosions." He was told that there would be additional nuclear detonations at Eniwetok during the spring. Arrangements were made to supply him with daily maps of the continental United States during the Eniwetok tests, showing the areas where radioactive material might be expected in the atmosphere and might be brought down to the ground by precipitation.

6. On March 12, 1951, the President of the Eastman Kodak Company wrote to Mr. Pike, saying in part: "This letter is written mainly to advise you that if the expenditures which may be required become substantial, or if there should be a considerable amount of damage to our products resulting from the Nevada tests or from any future atomic energy tests authorized by the Commission or any department of the Government, we will very likely have to file claims for redress against the Government." (See Appendix "D" for full text.) This was answered on May 1, 1951, by Mr. Pike (Appendix "E") with an outline of what was being done to assist in minimizing undesirable effects from the test and an assurance that the Atomic Energy Commission was keenly aware of the problems of the photographic industry.

PREPARATIONS FOR GREENHOUSE

7. On March 21, 1951, representatives of the AEC Divisions of Military Application and Research and the New York Operations Office attended a meeting in New York of the Committee on Radioactivity of the National Association of Photographic Manufacturers. A public announcement that tests were to be conducted at Eniwetok had been made by the AEC the previous day. During the

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meeting, the effects of radioactive material from the Nevada tests were discussed and arrangements were made for the New York Operations Office to assist the photographic industry in detecting and measuring any radioactive contamination that might result from the Eniwetok tests. "Q" clearances were initiated for the following members of the Committee: Dr. E. K. Carver of the Eastman Kodak Company, Dr. E. B. Middleton of the DuPont Company, and Mr. H. W. Morreall, Jr., of the Ansco Division of General Aniline and Film Corporation. The National Association assumed the responsibility of keeping other photographic companies informed of the problems which might arise and the precautionary measures to be taken.

8. A field trip by Mr. A. E. Gorman, Sanitary Engineer, Division of Engineering, AEC, was made to Rochester in April, 1951, by arrangement between the Division of Military Application and the Eastman Kodak Company, with the objective of giving assistance with regard to water and air purification. A copy of his report is attached as Appendix "F". Mr. Gorman pointed out certain inadequacies in the water purification system of the Eastman Kodak Company and brought to their attention recently developed refinements in air cleaning at AEC installations which might be helpful. He specifically referred Eastman Kodak representatives to AEC sponsored research in water purification and air cleaning at the Oak Ridge National Laboratory, the Massachusetts Institute of Technology, and Harvard University and subsequently supplied them with copies of reports on this research. Mr. Gorman invited a representative of Eastman Kodak to attend the AEC seminar on air cleaning held at Harvard in June, 1951, and this invitation was accepted.

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9. During GREENHOUSE, daily maps showing possible contaminated areas in the United States were sent as promised over the period of the operations to Dr. Webb at the Eastman Kodak Company and to the New York Operations Office. This series of maps began on April 11 and ended on June 11. A letter of June 15 from Dr. Webb (Appendix "G") expressed his appreciation for this service. Some contamination was detected by the photographic industry during GREENHOUSE but, as far as we know, there was no serious damage to photographic supplies.

[redacted] PREPARATIONS FOR BUSTER-JANGLE

10. A meeting was called in Washington on August 28, 1951, by the Division of Military Application to alert representatives of the photographic industry in regard to the BUSTER-JANGLE tests. Present were Dr. Carver of Eastman Kodak, Dr. Middleton of DuPont, Mr. Morreall of Ansco, and representatives of the Air Force, the AEC Divisions of Biology and Medicine and Military Application, and the New York Operations Office. At that meeting the conferees (all "Q" cleared) were given the location and the months of BUSTER-JANGLE. This was classified as Confidential, Not Restricted Data, but permission was given to disseminate it to those persons within the photographic industry who needed the information to protect their parts of the industry. (The fact that tests were to be conducted at Nevada was publicly announced by the AEC on the day of the meeting.) The conferees were also given, for their own information only, a brief statement of the nature of the shots (air drop, tower, etc.) and were promised a list of shot dates when the latter were fixed. This was later given them. The representatives of the photographic industry stated that the above information, coupled with maps showing predicted and confirmed cloud tracks sent at

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intervals, would enable them to schedule their stockpile buying so as to avoid using contaminated materials. The general attitude of the representatives of the photographic industry toward the possibility of serious damage seemed to be considerably relaxed at this meeting in comparison with some of the fears they had expressed at earlier meetings.

11. The New York Operations Office worked out a plan in conjunction with the Division of Biology and Medicine for the sampling of radioactive fall-out at 50 ground stations of the Weather Bureau. Airborne samplers were operated by the Air Force for New York Operations under the same plan. Following the operations, the two sets of data were to be summarized and evaluated and comparisons drawn. Particular interest centered in fission product identification, activity, and particle size and distribution.

12. As agreed, a series of daily prediction and confirmation maps of cloud tracks were sent to Dr. Webb at Eastman Kodak, Dr. Middleton at DuPont, and Mr. Morreall at Ansco and to the New York Operations Office for each shot during BUSTER-JANGLE. This series was started on October 24 and discontinued on December 3 as the last JANGLE cloud passed out to sea off the East Coast.

13. On November 13, 1951, the Manager of New York Operations sent in a summary of the situation regarding the photographic industry (Appendix "H"). The Eastman Kodak Company had stopped production on fast photographic papers and on X-ray film interleaving paper as a result of radioactive contamination. The Defender Division of the DuPont Company stopped operations for one day, November 1, while snow was removed from the side-

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walks in front of the building and the roofs adjacent to the Coating Department were washed. Arrangements were made for Dr. Rolf Eliasson of the Sanitary Engineering Department of the Massachusetts Institute of Technology to serve under his AEC contract as consultant to the photographic industry through the National Association of Photographic Manufacturers in connection with the filtration of water to remove fission products.

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SUMMARY AND CONCLUSIONS

14. Following the initial fall-out of radioactive material over the Northeastern United States from RANGER, representatives of the photographic industry were given information and assistance to enable the industry to make preparations to protect against radioactive contamination. They were also given advance information on future test dates to enable purchases of uncontaminated materials to be planned. Finally, they were given information promptly after each test on the expected distribution of radioactive material in order to anticipate local contamination and take preventive action where called for.

15. It appears that all feasible steps have been taken by the Atomic Energy Commission to decrease the effects on the photographic industry of radioactive contamination from atomic weapon tests.

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ANNEX "A"

HEADQUARTERS
JOINT TASK FORCE SEVEN

21 April 1948

MEMORANDUM FOR: Admiral Parsons

SUBJECT : Site for Atomic Bomb Experiments.

1. From a meteorological standpoint, there are three basic requirements for a suitable site for atomic bomb experiments. These are:

a. There should be a reasonable frequency of occurrence of cloud or weather conditions to meet the operational requirements for the experiment, Thus, if it is essential to have clear skies for the test, a reasonable percentage of clear sky days should be recorded in the climatic record for the site. Or if it is desirable to explode the bomb in a rainstorm, a reasonable frequency of occurrence of rainstorms should be recorded.

b. Wind conditions from the surface to stratospheric levels should be such that there can be no possibility of subjecting personnel to radiological hazards or surrounding land or water area to unintentional radioactive contamination.

c. The mechanism of meteorological processes for the site should be adequately understood and the weather predictions for the site demonstrated to be of a high and reliable accuracy..

2. The Marshall Islands in the main do not meet these meteorological requirements.

a. First, partly cloudy conditions, generally four to six tenths cumulus base 2,000 feet and tops variable to 10,000 feet prevail over the Islands. Scattered light showers are common throughout the year. For experiments requiring a minimum of cloudiness, this tropical area is a poor choice. Probably the most vivid example of the sensitivity of the prevailing cloudiness to an experimental operation was the Able-day test at Bikini. For this test, a minimum cloudiness was almost mandatory. A bomb drop would have been impossible had the average Marshall Island cloudiness prevailed on Able-day. In the practice days leading up to Able-day, bomb dropping aircraft frequently aborted for failure to see the target because of clouds. The fact that Able-day was successful does not alter the fact that for an average expectancy, the mission should have failed and that a long postponement may have occurred before a suitable day for the mission would have arrived.

b. The wind conditions in the Marshall Islands have a complex structure which tends to complicate the radiological safety pattern. Winds blow from the east from the surface to near 20,000 feet, then shift to the west above this level to heights of 50 or 60,000 feet, and then again blow from an easterly direction in the stratosphere. This complex upper wind structure, when interpreted into diffusion of radioactive debris, requires a readiness for evacuation of personnel by Navy ships for every test.

c. There are no known satisfactory methodologies for forecasting in tropical areas. The nature of atmospheric processes is incompletely understood and, as a result, the prediction of winds, clouds and rain cannot be accomplished with a reliable accuracy.

3. Further, because of the paucity of existing weather stations in the Marshall Islands an undertaking of an atomic bomb experiment in this area requires the support of a very sizeable meteorological force. The existing weather stations require augmentation by personnel and specialized equipment for making very high level atmospheric soundings. New stations have to be established generally on uninhabited atolls. For the SANDSTONE Operation, approximately three hundred thirty (330) officers and men were required for meteorological

support. Despite this number of men, there can be no high assurance that the predictions for twenty-four (24) hours and beyond for critical test days will be accurate because of the incomplete understanding of tropical meteorology.

4. In considering a possible site in the United States for atomic bomb experiments, it would appear that the most cogent requirement would be one of safety. This requirement can be easily met by choosing a climatic region where the winds to stratospheric levels show a consistent direction such that there can be little or no probability of radioactive debris unintentionally contaminating personnel and surrounding land and water areas. Because the United States is predominantly under the influence of prevailing westerly winds, it seems obvious that the eastern coast areas of the United States may provide a suitable site. For example, the coastal areas of North Carolina are influenced by prevailing west to northwest winds to at least 50,000 feet throughout all seasons of the year.

Along the coastal areas of North Carolina, there are frequent storms, but these alternate with periods of fair weather with small amounts of cloud. Predictions of weathe and winds can be made generally with high accuracy for twenty-four (24) hours and with moderate accuracy for as much as six (6) days in advance. There is also the importa advantage of the existence of an adequate meteorological net work which can provide high level soundings with a minimum expenditure of effort.

/s/ B.G. HOLZMAN
Colonel, USAF
Staff Meteorologist,
JTF-7

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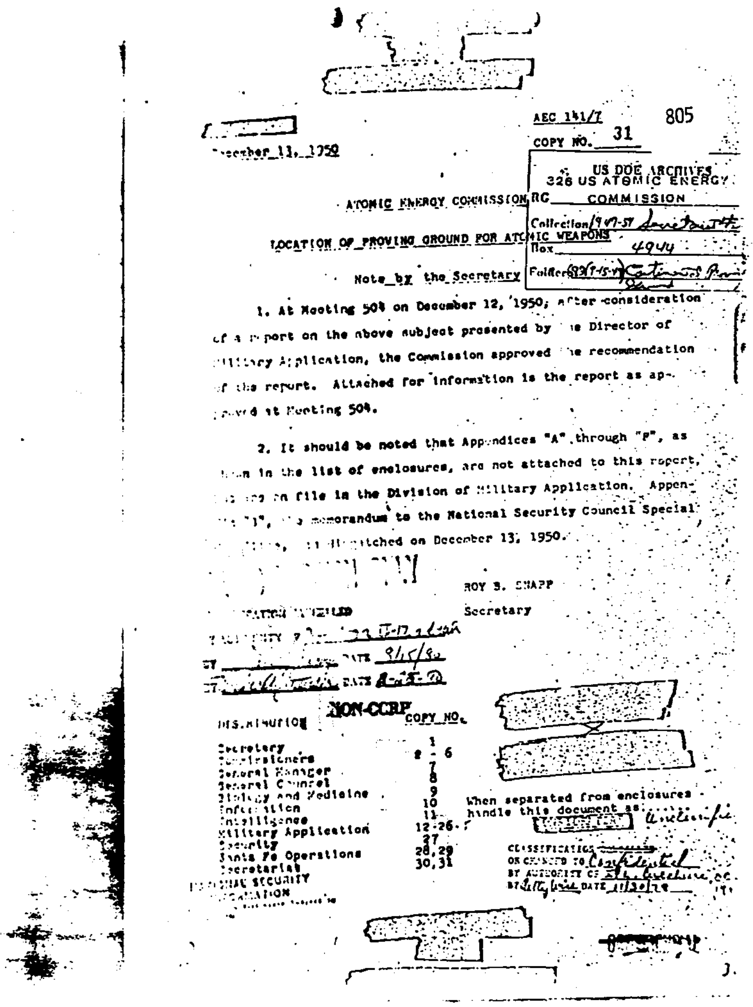

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ATOMIC ENERGY COMMISSION

LOCATION OF PROVING GROUND FOR ATOMIC WEAPONS

Note by the Secretary

1. At Meeting 504 on December 12, 1950, after consideration of a report on the above subject presented by the Director of Military Application, the Commission approved the recommendation of the report. Attached for information is the report as approved at Meeting 504.

2. It should be noted that Appendices "A" through "F", as shown in the list of enclosures, are not attached to this report, are on file in the Division of Military Application. Appendix "1", a memorandum to the National Security Council Special tee, was dispatched on December 13, 1950.

ROY B. SNAPP
Secretary

DATE 9/5/90

DATE 8-15-92

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ATOMIC ENERGY COMMISSION

SELECTION OF A CONTINENTAL ATOMIC TEST SITE

Report by the Director of Military Application

THE PROBLEM

1. To review the requirements for a test site additional to Eniwetok Proving Grounds for testing atomic weapons, and to make recommendation to the Special Committee of the National Security Council for the early development and use of at least one location.

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BACKGROUND

2. The desirability of a continental atomic test site for the post-World War II Weapons Program was recognized as early as 1947. Such a proposal was considered during the early planning for Operation SANDSTONE. General Hull, as SANDSTONE Task Force Commander, later recommended consideration of a U.S. site following his experience with off-shore operations and extended supply lines during Operation SANDSTONE in 1948. As a result of General Hull's recommendation, the Armed Forces Special Weapons Project undertook a study of possible U.S. test sites, and this study, alled "NUTMEG", is attached as Appendix "B". This study, while ot conclusive but indicating the arid-Southwest as a preferred ocation, was laid aside in early 1949 by the AEC for possible ater consideration in the event of an emergency. [redacted]

3. At the request of Chief of Staff, USAF, the Armed Forces pecial Weapons Project again in the summer of 1950 studied the

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subject of a continental site with the view of finding a suitable location for GREENHOUSE should use of Eniwetok be denied. The study provided the same indication that the Southwestern United States area was preferred, and gave population figures, corrected from 1950 Census data. Meteorological conditions were shown to be excellent for radiological safety in restricting the area down-wind which may be contaminated from cloud fall-out. The Joint Task Force Three Alternate GREENHOUSE plan called for an "austere" operation in that area. An examination of the Las Vegas Bombing and Gunnery Range in Southwestern Nevada was made in support of this plan by the firm of Holmes and Narver, by contract for AEC. Their report (Appendix "C") covers those facts which are apparently pertinent to the conduct of a GREENHOUSE-typ operation.

4. Recent discussions in the AEC and the Department of Defense have led to a National Security Council directive of November 14, 1950, (Appendix "A") which directs the AEC, with Department of Defense assistance, to make this study and recommend a site for early development and use. A survey of the Las Vegas range, more complete than the Holmes and Narver examination, is now being conducted for the AEC by the Office, Chief of Engineer The results of this survey will become available during the latt part of December, 1950.

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DISCUSSION

5. In considering the need for an additional test site tw fundamental uses are seen. The first is that of a site supplemental to Eniwetok and Amchitka for some purposes, capable of serving economy in terms of time, personnel, equipment and mone and, above all, to expedite the weapons development program. T second is that of an emergency alternate to overseas sites, at location where its basic security and general accessibility ca

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be jeopardized by enemy action.

6. Only Partial Solution. It should be noted, that, at the present time, no site within the United States can be considered a completely satisfactory alternate to overseas sites. If a relatively long time for site development were acceptable, on-continent sites outside the U.S., with suitable international arrangements, could offer advantages of remoteness for the high-order yields to be anticipated both in the fission and thermonuclear fields, and for the special radiological safety problems introduced by an experiment such as the underground shot now planned for Amchitka. The current urgency, however, centers on a site of much smaller capacity.

7. Criteria for New Site. The factors controlling the selection of a continental atomic test site include primarily the following:

a. Radiological Safety. Population density, favorable meteorological conditions and ability to predict them accurately.

b. Physical Requirements. Size, climate, topography, location and water.

c. Availability. High desirability of using Government-controlled land to expedite initiation of development for use at the earliest practicable time.

d. Operational Facilities. Good air and surface transportation, communications, power, nearby civilian community as a base for logistic support.

8. Radiological Safety. For the protection of the population existing near the test site, favorable meteorological conditions and wind structures, accompanied by the capability for accurate predictions, are necessary to permit firing of test shots at times selected for desired direction of drift and conditions of fall-out. Meteorological studies of various areas, similar to those included in the "NUTMEG" study have eliminated certain areas from further consideration, due to poor wind structure, frequency

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of unpredictable weather changes or low percentage of days on which desirable meteorological shot conditions may be anticipated.

9. It is recognized that the problem of radiological safety is most critical in site selection. Not only must high safety factors be established in fact, but the acceptance of these factors by the general public must be insured by judicious handling of the public information program. Safety hazards such as those which existed for the 1945 test at Trinity can be greatly reduced by such means as paving the zero area to reduce dust volume, using higher towers, and shooting under weather conditions forecast for maximum safety instead of to a rigid schedule as was necessary for military reasons at Trinity. By such means as these, and taking advantage of more sparsely populated areas, it is believed certain continental sites would permit a substantial improvement in predicted safety over the Trinity shot (Appendix "F").

10. Finally, two broad conclusions have been reached by authorities who have considered this subject. These are:

> a. Shots up to 25,000 tons TNT equivalent can certainly, and shots up to 50,000 tons TNT equivalent can probably, be detonated within acceptable safety limits in the continental U.S. ?
>
> b. Results of actual shots and relatively low-order energy release should be utilized as a basis for estimating acceptable limiting yields for later shots, and the above limits may eventually be raised considerably.

11. These two conclusions have been considered at length, and there seems to be no doubt among experts that a continental site can be used safely for atomic testing of shots of relatively low order yields. There will of course be a specific examination of radiological safety factors in connection with and before each planned experiment, in the light of the nuclear composition and predicted performance of the weapon in question. Meanwhile, approval of a continental site for development and use can be sought without delay.

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12. Physical Requirements. The second criterion (paragraph 7) involves the physical characteristics of the area, such as size, climate, topography, water and location. The size of the area selected should permit the installation of several firing points with 5-10 miles between them or between each firing point and the control point. Thus, an area of several hundred square miles is essential. The climate of the area should permit the preparation and execution of experiments on a reasonably predictable schedule at any time during the year. The topography of the land should be flat, or have smooth and regular contours for ease and economy of construction and operation, as well as for visibility for photographic collection of data. Water supply sufficient for a base camp of approximately 2000 people is also a prime requisite. A geographical location as close as possible to the Los Alamos Laboratory, to enable accelerating the pace of the weapons development program is obviously a ch
such desirability that it could outweigh partial
other respects.

13. Availability. Availability of the necessa
third criterion. For reasons of time it is almost
land already under the control of the U.S. Governmen
thus avoiding complicated acquisition processes, and
be served thereby. This is also desirable from the security and public relations points of view.

14. Operational Facilities. Operational facilities constitute the fourth important criterion. There should be good transpor tation, good communications, and adequate electric power. A nearl community on which to base transient living and logistic support for general construction operations, as well as for the interim support of the site, can add much to the economy and ease of developing and operating a test site of this nature.

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15. Foreign Sites Eliminated for the Present. In summary, the selected site must satisfy radiological safety requirements, contain not less than four or five hundred square miles of reasonably level land already under governmental control, be located as near Los Alamos as practicable, and have a number of the facilities required for operations already in place. These criteria, as applied to the site which is urgently needed now, point definitely to the continental United States rather than to possible sites in Deleted Alaska, Deleted which might have added advantages of remoteness. No overseas site is wanted now in lieu of Eniwetok or Amchitka.

16. Sites Within the United States. Within the United States, there are several areas whose use for atomic weapons testing has been considered in various surveys and discussions. These areas have been initially screened on the basis of comparative radiological safety, favorable and predictable weather conditions, location and availability. There have remained for final consideration, after screening, the following areas:

a. Alamogordo-White Sands Guided Missile Range in New Mexico (which contains the Trinity Area).

b. Dugway Proving Ground-Wendover Bombing Range, in Utah.

c. Las Vegas-Tonopah Bombing and Gunnery Range, Nevada.

d. Area in Nevada, about fifty miles wide and extending from Fallon to Eureka.

e. Pamlico Sound-Camp Lejeune area, in North Carolina.

17. Of the above areas, the first three are partially or wholly under the control of the Department of Defense, on a temporary withdrawal basis, and permanent withdrawal has been requested by the Office of the Chief of Engineers. Since the fourth and fifth areas are not Government-controlled, and there are

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indications of some delay in acquiring the necessary land, they were also dropped from further consideration. In this connection, it should be noted that recent reviews of the weather data for the Carolina Coastal area, which has certain advantages for the purpose in mind, have revealed that the apparently favorable meteorological conditions of wind and weather structures are based on average figures which, in reality, are seldom met. Examination of specific records, day by day, points up the strong possibility of long delays during a test operation while awaiting desirable weather conditions.

18. Las Vegas Best of Remaining Sites. Of the three remaining sites considered (Dugway, Las Vegas and White Sands) the latest AEC review confirms the judgments already expressed by the AFSWP, Los Alamos Scientific Laboratory and the Manager, SFO, that the Las Vegas location most nearly satisfies all of the establishe criteria for a continental atomic test site.

19. A comparison of total populations in a base area site plus a 90 degree possible fall-out sector, to a radius of 125 miles down-wind from site, shows the Las Vegas site as involving the fewest people, with Dugway having by far the most (Salt Lake City), White Sands falling between the two in this respect. In total area, the Las Vegas Range is the largest of the three, although this factor is important principally from the standpoint of Government-controlled security and radiological monitoring. White Sands is closest to Los Alamos, but logistic and base camp facilities and capabilities are inferior to those for the Las Vegas site. Transportation and communication are good at Dugway but not in the Western portion of the area where shot sites would best reduce the radiation hazards to the large population areas further east.

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20. The advantages of the Las Vegas site have been listed in the Los Alamos Scientific Laboratory study attached (Appendix "F"). This site combines existing base facilities and transportation capabilities with required physical features and immediate availability. In addition, the problem of radiological safety is at once smaller and more easily controlled at and around this location than at either Dugway or White Sands. Finally, requirements and conditions at the Las Vegas location are not only superior relative to the other two sites, but are believed to be entirely acceptable in the positive sense for some of the most important tests now foreseen in the weapons program.

21. The Commission budget now before Congress contains $1,000,000 for the initiation of development of a continental test site.

CONCLUSIONS

22. It is concluded that:

a. There would, of course, be outstanding advantages in having an atomic test site on the North American continent for a wide range of full-scale tests from, say, 1000 ton TNT equivalent to 500,000 ton TNT equivalent, or more. However, at present it is clear that site acquisition and logistic problems preclude consideration of remote continental sites, in Deleted Deleted or Alaska, for instance, as available for early and efficient use. On the other hand, less remote continental sites present questions of radiological safety that have not yet been answered for very high energy release and other special tests. Study and investigation should continue for an all-purpose on-continent site, as the body of information on full-scale testing increases, and as the world situation may change, but that is not the urgent problem of the moment.

b. The over-riding requirement now for rapid progress in the weapon development program is to have a supplementary site at which critical tests involving relatively low orders of energy release may be conducted without elaborate organizational and logistic arrangements. This sort of testing is an intimate part of the weapon research program and should be regarded as a routine laboratory activity.

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c. This site must by definition be readily accessible to Los Alamos by land and air. It must also have reasonably regular topography, offer adequate radiological safety, and it should be economical to prepare and operate. Radiological safety is primarily a matter of favorable and predictable meteorology and sparseness of population in the direction of prevailing winds.

d. In present circumstances, with particular regard to the present and desired pace of the weapons program, such a site should be on land already Government held and available for immediate development.

e. Site requirements can be met in the Southwestern U.S., specifically at the Las Vegas Bombing and Gunnery Range (Tonopah) (Appendix "E"), where it is certain that some of the most urgent tests now planned can be conducted with a degree of radiological safety substantially greater than that which obtained for the Trinity test in 1945. (Appendix "B")

f. Site preparation should begin immediately. A few low order test detonations are now likely to be required within three months.

g. Each atomic explosion at this site should be subjected to a separate radiological safety determination by recognized experts. It is possible that as the test program progresses, tests of very high energy release and of special nature may emerge as feasible, but it seems wise to limit the objectives as regards early tests.

RECOMMENDATION

23. That the Atomic Energy Commission:

a. Approve the requirement for continental test site;

b. Approve the selection of the Las Vegas site for immediate development and early use as a continental atomic test site;

c. Approve forwarding the memorandum of recommendation (Appendix "G") to the Special Committee of the National Security Council.

[redacted] [redacted]

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LIST OF ENCLOSURES

APPENDIX "A"

Memorandum from Executive Secretary, NSC to Secretary of State, Secretary of Defense and Chairman, AEC.

APPENDIX "B"

Report of the "NUTMEG" Study.......AFSWP.

APPENDIX "C"

Report to the AEC Concerning an Emergency Proving Ground - Holmes and Narver Company.

APPENDIX "D"

Letter from Dr. Bradbury, Dir., LASL, to General McCormack, Dir., DMA, USAEC on the importance of the Laboratory development plans and test needs.

APPENDIX "E"

Report by Dr. Reines of the 1 August 1950 Radiological Safety Conference. LAB-J-1279.

APPENDIX "F"

Memorandum from J-Division, LASL, concerning the desirability of the Tonopah Range. LAB-J-1609.

[illegible]

APPENDIX "G"

Draft memorandum to the National Security Council Special Committee regarding MERCURY.

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APPENDIX "G"

(12-13-50)

UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D. C.

[redacted]

MEMORANDUM For The Special Committee of the National Security Council for Atomic Energy Matters

Subject: ADDITIONAL TEST SITE

As directed in National Security Council memorandum dated November 14, 1950, the Atomic Energy Commission has made a review of possible locations for the required additional atomic weapons test site. The Department of Defense has assisted the Atomic Energy Commission in this review.

At the beginning, it may of course be said that there would be outstanding advantages in having a continental site for all atomic weapons tests, involving a wide range of energy release of from, say, 1000 to 500,000 tons TNT equivalent, or more, and for tests of special natute. However, there are problems of site acquisition and logistics which preclude consideration for early and efficient use of very remote sites, as in Deleted or Alaska, and less remote continental sites present questions of radiological safety for tests of very high energy release and other tests which might involve a high order of radiological contamination. These latter questions may be answered satisfactorily as test knowledge increases through experiments, and as the world situation may develop, but they are not satisfactorily answered at present.

The Commission has therefore, after study, limited itself at this stage in its serious examination of possible sites to those which might meet the urgent requirements of the immediate weapons development program. The essential need now is for a site at which a few relatively low order detonations may be done safely and with minimum non-productive cost in time, effort and money at the earliest possible dates, preferably within the next two to three months. The Commission budget now before Congress contains $1,000,000 for the initiation of development of a continental test site.

The criteria for such a site include primarily: ready accessibility to the Los Alamos Laboratory by land and air, good communications, adequate radiological safety, reasonably regular topography and prospects of economy of preparation and operation. There are two general areas within the continental U.S. where it is believed a considerable portion of the expected AEC testing program could be conducted without undue public radiological hazard. These are the South Central Atlantic Coastal area and the arid Southwest. There are four locations within these two areas where some of the facilities needed for operations are already in existence, so that a site could be developed for atomic tests at reasonable cost. These locations are:

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[redacted] [redacted]

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a. The Las Vegas, Nevada, Bombing and Gunnery Range.

b. The Dugway, Utah, Proving Ground.

c. The White Sands, N. M., Proving Ground (contains the Trinity site used in 1945).

d. The Camp Lejeune, N. C., area, North Carolina.

The Las Vegas site (see map attached*) has been selected as the most desirable. It has the following advantages:

a. The site is within easy reach of the Los Alamos Scientific Laboratory.

b. The weather and terrain conditions are such that it will be possible to use the site at any time during the twelve months of the year.

c. An atomic weapons test site is immediately available within the approximately 5400 square miles of Government-owned land currently in use by the U. S. Air Force. It is possible to establish test points which will not unduly restrict continued practice bombing and gunnery operations except during actual test periods.

d. Meteorological conditions and population density are such that some of the most urgent atomic weapons tests can certainly be conducted well within acceptable limits of public radiological safety. Each specific test operation would of course be subject to examination and approval by recognized experts.

e. Many of the buildings, power supply requirements, transport and communications lines, etc., required for operations already exist at the Las Vegas range.

In comparison with the Las Vegas site, the Carolina Coast site, in addition to the disadvantage of its relatively great distance from Los Alamos, does not have the necessary Government-controlled land area, while Dugway and White Sands do not provide quite so high a degree of radiological safety.

It should be noted that development of the Las Vegas range as an atomic weapons test site would not eliminate the current requirement for use of Eniwetok, Amchitka or some other similarly very remote site for tests where the radiological hazards involved may be beyond the limits acceptable in the United States. Thus, there remains a requirement of some urgency to find a secure site alternate to Eniwetok and Amchitka for use in an emergency which may deny the use of Eniwetok or Amchitka. This point will continue to receive attention.

The Atomic Energy Commission recommends approval by the National Security Council of the development of a portion of the Las Vegas Bombing and Gunnery Range as an atomic weapons test site,

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*. Secretariat Note - On file in Division of Military Application.

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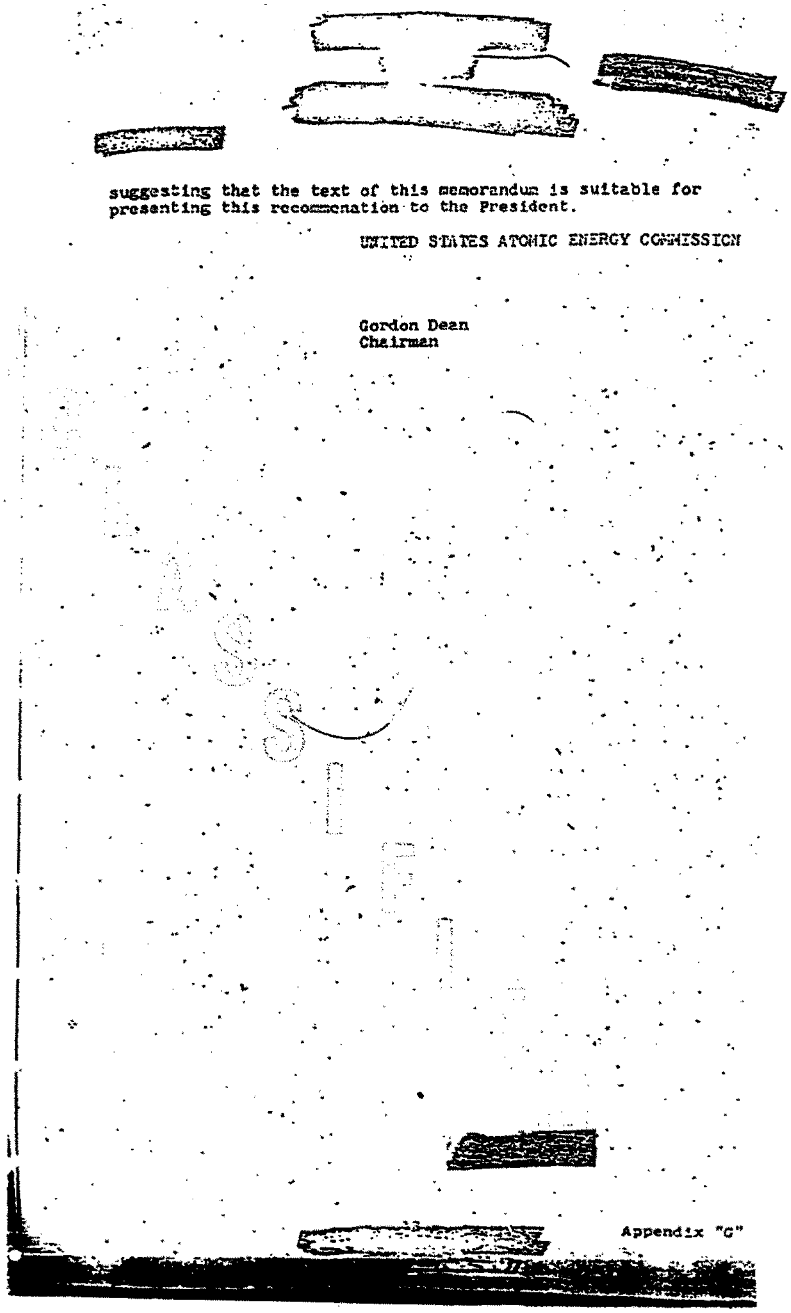

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suggesting that the text of this memorandum is suitable for presenting this recommenation to the President.

UNITED STATES ATOMIC ENERGY COMMISSION

Gordon Dean
Chairman

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Appendix "G"

ATTACHMENT

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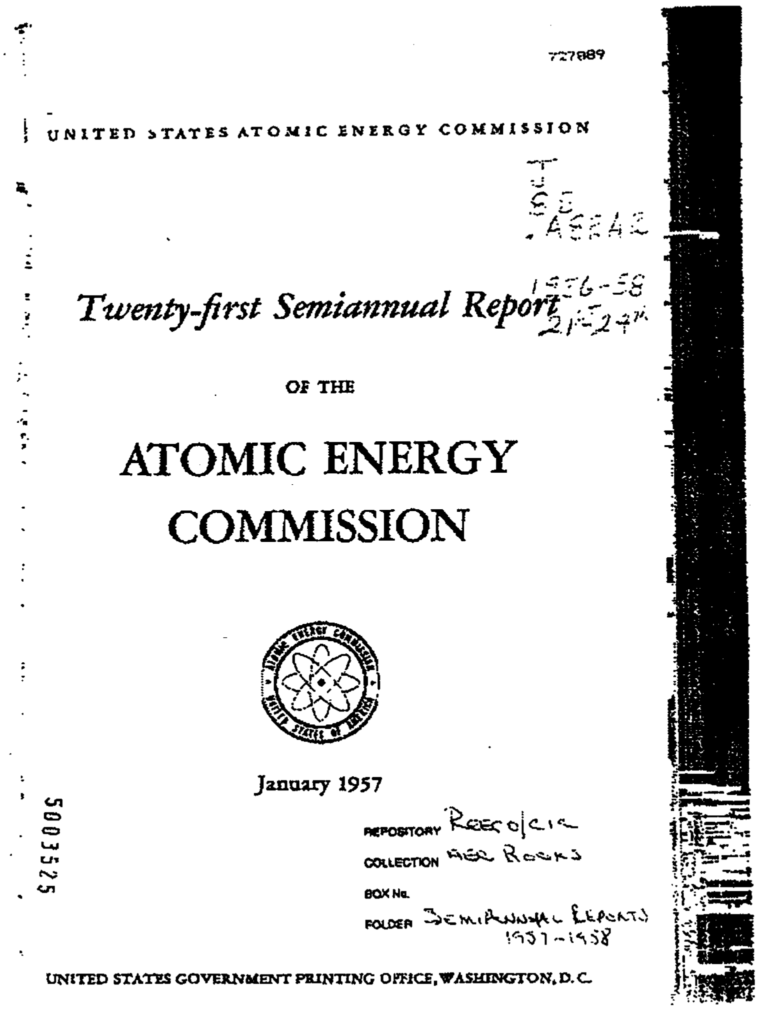

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UNITED STATES ATOMIC ENERGY COMMISSION

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Twenty-first Semiannual Report

OF THE

ATOMIC ENERGY COMMISSION

January 1957

REPOSITORY Record/CIC
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UNITED STATES GOVERNMENT PRINTING OFFICE, WASHINGTON, D.C.

b) Intensive sampling of soil, plants, animals and air for 2 to 4 weeks immediately after a fall-out contamination with special emphasis on occurrence of certain fission products. This study takes place simultaneously in several areas along the mid-line of fall-out to a distance of approximately 300 miles. There is also a continuous sampling program carried on apart from this test activity.

c) Study of the characteristics of extended fall-out patterns by aerial survey.

Eniwetok Proving Ground. Similar precautions are taken during the Pacific tests.[*] Since larger nuclear devices are tested in the Pacific, the warning area covers nearly 400,000 square miles. This area is surveyed by surface ships and aircraft in advance of each test. Any ships that enter it are warned away. Weather and fall-out prediction units function much the same as in Nevada. Nine stations, in addition to the eight that operate regularly, are established for each test series.

Following detonation, aircraft follow the radioactive cloud and others perform surveys over land and sea areas to chart any residual activity. The populated islands of Wotho, Ujelang, and Utirik, were monitored by personnel of the U. S. Public Health Service during Operation Redwing (spring 1956 series). Use is made of a variety of ships, skiffs and buoys containing recording equipment, and large-scale marine and land surveys are made to measure any environmental contamination.

Worldwide monitoring. The monitoring programs do not stop at the areas around the test sites. During all test operations, 80 monitoring stations are maintained in the United States and an additional 88 have been maintained in 46 countries and territories throughout the free world through the cooperation of the U. S. Weather Bureau, U. S. Public Health Service, State Health Departments, and the Commission. Other monitoring stations are being added abroad. All these stations collect fall-out particles with gummed paper and send them for counting of radioactive material deposited to the Commission's Health and Safety Laboratory. In addition, about 35 of the Public Health Service and Commission stations in the United States make air collections and some rain analyses. These latter stations are part of a nationwide immediate operative system to supply data on short notice.

Assistance to photographic industry. The Commission, in recognizing the potential operational problems to the photographic industry

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[*] A full report on protection methods during Operation Redwing is given in Appendix Twentieth Semiannual Report (January–June 1956).

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through a possible contamination or fogging of films from radioactive fall-out due to weapons tests, has furnished information to them since 1951 through the office of the executive secretary of the National Association of Photographic Manufacturers. In order to assist the industry in establishing production schedules, the Commission wherever feasible has provided statements of periods during which no United States tests are planned and advance notice of as much as 4 months of tests which might affect the photographic industry.

During test series frequent forecasts of contaminated areas based on meteorological data have been furnished, enabling processors to take precautions. The Commission has also consulted with the technical Committee on Radioactivity of the Manufacturers' Association on matters of radiation detection, protective measures, transportation, and waste disposal.

Fall-out data. Any nuclear detonation forms immediately about 60 different radioactive substances representing some 35 elements. Most of these substances initiate decay chains consisting of several isotopes so that eventually 170 isotopes may be produced, with radioactive half-lives ranging from a small fraction of a second to many years—that is the time during which about half the atoms in any given quantity of radioactive material undergoes radioactive decay.

If the nuclear detonation occurs high in the air, the radioisotopes become associated with fine particles that settle relatively slowly to the earth, so that the activity of the short-lived isotopes decays and the particulate matter is widely dispersed. Thus, the immediate fall-out will be relatively small. Where the fireball from a nuclear detonation intersects the ground, the radioisotopes will become principally associated with larger particles of matter which fall relatively rapidly, thus producing higher concentrations of radioactivity in nearby areas. Measures to reduce local fall-out include using higher towers and by stabilizing surface soil around the towers.

Another factor which affects the area, the amount, and the timing of the fall-out is, of course, the energy yield of a detonated device. In the kiloton range of bursts, radioactive material will be confined to that section of atmosphere known as the troposphere where winds will mix and dilute materials rapidly, where clouds form, and precipitation will fairly rapidly strip out the radioactive material. Bomb debris in this case may travel around the world but will be confined largely to the approximate degrees of latitude in which the explosion took place.

Radioactive materials driven into the stratosphere from detonations of larger weapons have a different pattern of fall-out from

ATTACHMENT

9

12-JUL-90

EXECUTIVE SUMMARY

Ninety-seven nuclear tests were detonated in the atmosphere at the Nevada Test Site (NTS) between 1951 and 1958, and four tests were detonated in the atmosphere in 1961 and 1962. The thyroid absorbed doses from ^{131}I that the American people received from 72 of those atmospheric tests, plus the thyroid absorbed doses from ^{131}I that the American people received from 10 cratering shots and from 8 underground tests that vented radioactive materials into the atmosphere, have been assessed for each county of the contiguous United States. The only tests which were not included in the dose assessment are those which did not result in any detectable off-site contamination and those which, in the absence of an established monitoring network, were estimated to have led to negligible contributions to the total thyroid dose on the basis of the yield and type of explosion.

The major exposure route to man is, for most people, the ingestion of cows' milk contaminated as a result of ^{131}I deposition on pasture. The thyroid doses from other, less important, exposure routes such as inhalation and ingestion of leafy vegetables, goat's milk and other foodstuffs also have been estimated, but, in general, may be important only for those persons who did not consume cows' milk.

The radiological importance of ^{131}I was not recognized until 1957. Therefore, very few measurements of ^{131}I in the environment and in man were available to carry out this dose assessment. The exposures were, for the most part, estimated for each test from measurements of beta activity deposited on sticky material (gummed-film) at up to about 100 sites across the United States, complemented with models of environmental transfer to man. A more detailed assessment was carried out near the NTS as a relatively high number of environmental measurements are available for that area.

Thyroid doses from ^{131}I were calculated for 14 age and sex groups ranging from the fetus to the adult male and female in each county. Within each age and sex group, thyroid doses have been calculated for particular population groups, defined according to consumption habits, in order to obtain insight on the range of thyroid doses that can be expected to have been delivered. However, the thyroid doses thus estimated are averages over relatively large population groups in each county and the thyroid doses received by specified individuals may substantially deviate from the average dose for the particular group considered when specific dietary habits and metabolic parameters are taken into account.

The estimates of the average thyroid doses, due to all tests detonated at the NTS, vary from 0 to about 100 rads, according to the population group considered, with an overall per capita thyroid dose of about 2 rad. The variability of the thyroid doses received in a given county from one population group to another, is about a factor of 1 to 500, depending on the age and sex group, and on the dietary habits assumed. The distribution of the thyroid doses received by a given population group in a given county is taken to be lognormal, and the associated uncertainty is calculated to range from 2 to 10 depending on the type of measurement made at the time of the test, environmental characteristics, milk distribution patterns, and dietary habits. It is stressed that thyroid doses to specific individuals are not calculated in this report, as they depend on the residence histories and on dietary habits which are characteristic of these individuals. However, if this information is available, the procedure to be used to calculate thyroid doses to specific individuals is provided.

Although the uncertainties attached to the thyroid dose estimates are relatively high, reasonable agreement exists between the thyroid doses calculated from this assessment and the thyroid doses derived from those few historical measurements of ^{131}I in the environment and in man which are available.

TECHNICAL SUMMARY

TS.1. INTRODUCTION

One part of Section 7(a) of Public law 97-414 directs the Secretary of Health and Human Services to "conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to ^{131}I that the American people received from the Nevada atmospheric bomb tests".

The National Cancer Institute (NCI) was requested to respond to this mandate. In so doing, a task group, established to assist the NCI in this effort, suggested that it might be possible to estimate, for each of the most important tests, the ^{131}I exposures from fallout for representative individuals and for the populations of each county of the contiguous U.S. during the time of the tests. About 100 of the tests carried out at the Nevada Test Site (NTS), with yields ranging from less than one kiloton to 74 kilotons of TNT, resulted in off-site detection of radioactive materials. The radiation exposures from 90 tests, representing about 97% of the total activity of ^{131}I that had been released into the atmosphere, have been estimated in this report.

The most significant atmospheric weapons tests with respect to fallout occurred in the 1950s, during which time most of the monitoring of environmental radioactivity consisted of gross β or γ measurements. Therefore, the estimation of ^{131}I exposures dating back to the 1950s must essentially be derived from the original measurements of gross β or γ activity, or from mathematical models.

Exposures to ^{131}I in fallout resulted mainly from the pasture-cow-milk foodchain. In the assessment of the ^{131}I exposures from that foodchain on a continental scale, estimates need to be made, for each of the approximately 3,100 counties in the contiguous United States, of:

- the activities of ^{131}I deposited on soil and vegetation,
- the amount of ^{131}I consumed by dairy cows and the resulting ^{131}I concentrations in cow's milk,
- the ^{131}I ingested by people, and
- the radiation absorbed doses from ^{131}I in the thyroids of people.

In addition, exposures to ^{131}I in fallout resulted from other, usually less important exposure routes (inhalation of ^{131}I-contaminated air, and ingestion of foodstuffs other than fresh cows' milk). These exposure routes are also considered in this report, but in a much less detailed manner.

TS.2. ESTIMATION OF ACTIVITIES DEPOSITED ON THE GROUND

Meteorological modeling and re-analysis of historical monitoring data are the two methods used to estimate the ^{131}I that was deposited on the ground following each test. For both approaches, the assumption is made that the ^{131}I was in particulate form, as were the majority of radionuclides produced in the atmospheric nuclear weapons tests.

TS.2.1. Meteorological modeling

The radioactive cloud that was formed after an atmospheric detonation near the ground surface usually was in the shape of a mushroom, extending from the ground surface to the highest layers of the troposphere, and occasionally reaching into the stratosphere. It contained hundreds of different radionuclides, including ^{131}I. The amount of ^{131}I produced in each explosion was derived from published information specific to each test. The ^{131}I activity per unit yield was found to be about 150 kCi kt^{-1} of fission for the tests considered in this report and the total activity of ^{131}I released into the atmosphere was estimated to be about 150 MCi.

The meteorological prediction of the ^{131}I deposition involves two steps:

(a) dispersion of the radioactive cloud across the U.S., and

(b) estimation of the amount of ^{131}I deposited on the ground.

TS.2.1.1. Dispersion of the radioactive cloud

The dispersion of the radioactive cloud has been analyzed for each important atmospheric test using routine weather maps which depict airflow at constant pressure levels. These maps, which were provided twice a day by weather services, were used to construct, at several altitudes ranging between 3 and 13 km, 6-h trajectories of air parcels originating at the Nevada Test Site and moving across the U.S. In general, trajectories at those various altitudes diverged in both direction and speed after leaving the detonation site. The radioactive cloud was often stretched by vertical wind shear to many hundreds of km before it left the U.S. This large shear resulted in great dilution of ^{131}I. Additional distribution was caused by lateral spreading of the cloud by eddy or turbulent diffusion which was assumed to occur at a rate of about 7 km h^{-1}. The meteorological model predicts the spatial coverage of the radioactive cloud at each 6-h interval and the ^{131}I activities per unit area contained in the radioactive cloud at each county centroid of the continental U.S. It is assumed in the model that at any given time the distribution of ^{131}I was uniform within the boundaries of the cloud segments created by lateral spreading and vertical shearing between the altitudes at which the trajectories were determined.

TS.2.1.2. Deposition on the ground

Deposition of ^{131}I on the ground results from two processes: impaction of aerosols on the ground surface (dry) and precipitation (wet). In the western part of the country, most of the deposition of ^{131}I was due to dry processes, since weapons testing generally was not allowed under atmospheric conditions such that wet deposition was likely to occur within a few hundred km from the NTS. That operational precaution, however, did not extend to the eastern part of the country, where most of the ^{131}I deposition occurred as a result of wet processes. In order to approximate the amount of rain that occurred across the country during the time period of interest, recorded daily rainfall amounts reported by the National Oceanic and Atmospheric Administration (NOAA) were averaged on a county basis.

The endpoint of the meteorological model is the estimation of the amounts of ^{131}I that are deposited by precipitation. This involves not only the knowledge of the daily rainfall amounts but also that of many other uncertain factors, among which are the efficiency of the rain-out process, the exact location of the radioactive cloud, the location and dimensions of the precipitating cloud and the physico-chemical form of ^{131}I. Because of the complexity of the problem, the values of the scavanging coefficient were established empirically on the basis of the relationships obtained between the predicted column content of ^{131}I in the overhead cloud and the ^{131}I deposition estimated from the monitoring data (gummed-film), which are discussed in the following section.

TS.2.2. Review and re-analysis of historical monitoring data

For counties near the NTS, the primary data are exposure-rate measurements using portable survey instruments. An extensive program of exposure rate measurements was carried out in a few counties near the NTS for several days following each test. These exposure rate measurements, together with other, less extensive, monitoring data, were evaluated and archived by the Offsite Radiation Exposure Review Project (ORERP) of the Department of Energy. From these data, a Town Data Base and a County Data Base were derived:

1. the Town Data Base (TDB) lists the time of arrival of the radioactive cloud produced by each test and the exposure rate normalized at 12 hours after detonation (H + 12) at 173 stations, representing inhabited locations, in 4 counties of Nevada (Clark, Esmeralda, Lincoln, and Nye) and in Washington County, Utah. The use of H + 12 as the standard time to report exposure rates is an agreed-upon convenience; fallout may have been deposited on the ground before or after H + 12;
2. the County Data Base (CDB) lists the estimated times of initial arrival of the radioactive cloud and the estimated exposure rates normalized at H + 12 in 24 subdivided areas of 9 counties in Arizona, California, Nevada, and Utah, along with similar information for 120 additional counties (i.e., not subdivided) in Arizona, California, Colorado, Idaho, New Mexico, Nevada, Oregon, Utah, and Wyoming.

Estimates of deposition of ^{131}I per unit area of ground were derived from the exposure rates normalized at 12 hours after detonation, together with the corresponding times of arrival of the radioactive cloud. The complete results are presented in the form of Tables as well as of Figures in the Annexes of the report.

Over the remainder of the U.S., monitoring of fallout deposition in the 1950s was carried out primarily by the Environmental Measurements Laboratory (EML) which, at that time, was called the Health and Safety Laboratory (HASL), in cooperation with the U.S. Weather Bureau.

The EML deposition network across the U.S. evolved gradually from the use of trays of water at 10 locations in 1951, to the use of gummed-paper collectors at 93 locations in 1952, and finally to the use of gummed-film collectors at about 100 locations until the end of the decade when it was discontinued. A "gummed-film collector" consisted of a 0.3 m x 0.3 m exposed area of gummed film which was positioned horizontally on a stand 0.9 m above the ground. Usually two films were exposed during a 24-h period beginning at 1230 GMT. The samples collected were ashed and counted for total β activity. The available gummed-film data that could be found in the HASL/EML archives, together with other less extensive fallout data, were used to derive depositions of radionuclides, including ^{131}I.

The resulting data set includes daily depositions of ^{131}I at up to about 100 locations in the U.S. during most of the atmospheric testing period. Those ^{131}I depositions are associated with information on the precipitation amounts occurring during the same 24-h periods.

TS.2.3. Estimation of the ^{131}I deposition in any given county

In order to estimate the daily ^{131}I deposition in any of the approximately 3,100 counties of the contiguous U.S., the following procedure, in which preference is systematically given to the monitoring data, has been applied:

- For the tests for which gummed-film data are available (from October 1951 to November 1958), the daily depositions of ^{131}I were obtained in most cases by interpolating between the counties with measured data using a kriging procedure.
- For the tests for which gummed-film data are not available (before October 1951 or after November 1958), meteorological modeling was used to estimate the daily depositions of ^{131}I in the counties where precipitation occurred during the passage of the radioactive cloud. Counties where precipitation did not occur during the passage of the radioactive cloud were assigned a zero deposition.

Daily depositions of ^{131}I per unit area of ground have been estimated in this manner for each of the 90 tests considered in the report. Figure TS.1 presents the estimated total depositions of ^{131}I per unit area of ground.

TS.3. ESTIMATION OF THE ^{131}I CONCENTRATIONS IN FRESH COW'S MILK

The transfer of ^{131}I from deposition on the ground to fresh cow's milk is relatively well documented. Figure TS.2 illustrates the parameters involved in that transfer. The time-integrated concentration of ^{131}I in milk (IC) corresponding to an estimated deposition density on the ground (DG) on a given day and in a given county was calculated as:

$$IC = DG \times F^{*} \times \frac{T_{eff}}{\ln 2} \times PI \times F_{m} \qquad (1)$$

Figure 5.1.

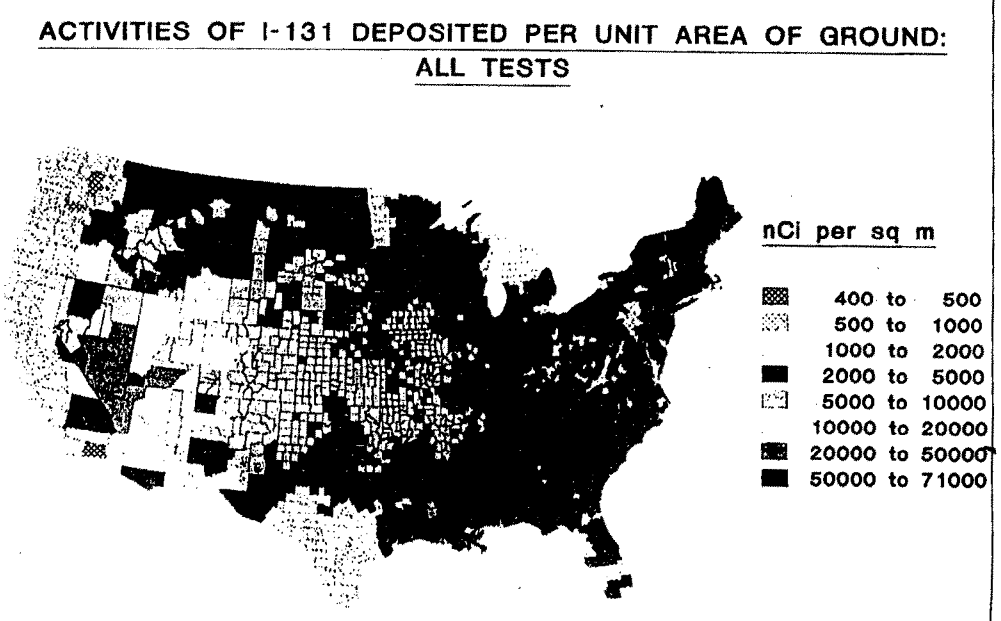
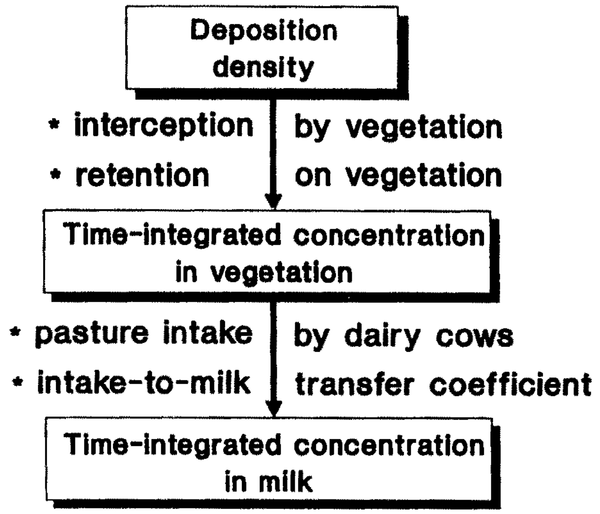

ACTIVITIES OF I-131 DEPOSITED PER UNIT AREA OF GROUND:
ALL TESTS
nCi per sq m
400 to 500
500 to 1000
1000 to 2000
2000 to 5000
5000 to 10000
10000 to 20000
20000 to 50000
50000 to 71000

Figure TS.2. Transfer of ^{131}I from deposition on the ground to fresh cows' milk.



in which F^* is the mass interception coefficient [m^2 kg^{-1} (dry weight)], T_{eff} is the effective half-time of retention by the vegetation (d), PI is the pasture intake [kg (dry weight) d^{-1}], and F_m is the intake-to-milk transfer coefficient (d L^{-1}). Each of these parameters will be discussed.

TS.3.1. Mass interception coefficient

The fraction of ^{131}I activity deposited on the ground which is intercepted by vegetation (F), usually called interception coefficient, depends, among other factors, on the meteorological conditions and on the type and density of vegetation. Values of interception coefficients obtained in laboratory or field experiments conducted under dry or light spray conditions with artificial radionuclides show a large range of variation between 0.02 and 0.82. A much narrower range of 1 to 4 m^2 kg^{-1} (dry) is usually obtained for the mass interception coefficient (F^*), defined as the interception coefficient (F) divided by the standing crop biomass (Y).

The interception coefficient is usually estimated as:

$$F = 1 - e^{-\alpha Y} \qquad (2)$$

where the numerical value of α, the foliar interception constant, is 2.8 m^2 kg^{-1} (dry weight) for elemental iodine and small-size aerosols under dry or light spray conditions. The value of F^* is then obtained as:

$$F^* = \frac{1 - e^{-\alpha Y}}{Y} \qquad (3)$$

There is evidence that the value of α decreases as the particle size increases and, therefore, that the interception coefficient decreases as the particle size increases. In the case of atmospheric nuclear weapons tests, large-size particles fall out near the detonation site and smaller particles are deposited as the radioactive cloud moves further away. The variation of α (m^2 kg^{-1}, dry weight) as a function of distance D (km) was expressed as:

$$\alpha(D) = 7.01\ 10^{-4} \times D^{1.13} \qquad (4)$$

Using this expression, the value of α increases with distance from the NTS and is approximately equal to TS.2.8 m^2 kg^{-1} (dry) for D = 1540 km. Beyond that distance, the value of α is taken to remain constant at TS.2.8 m^2 kg^{-1} in order to remain consistent with the value obtained from equation 2 for elemental iodine and small-sized aerosols.

All of the laboratory and field experiments were conducted under dry or light spray conditions and do not, therefore, provide any information on the values to be expected in the case of moderate or heavy rainfall. On the basis of experimental studies on the initial retention of rainwater by vegetation, it is proposed that the variation of the mass interception coefficient as a function of the rainfall amount P (mm) can be estimated by:

$$F^* = E + \frac{S}{P} \qquad (5)$$

where E = 1.3 m^2 kg^{-1} (dry weight) is the in-storm evaporation fraction per unit areal density of vegetation, and S = 16 mm kg^{-1} (dry weight) m^{-2} is the rainfall storage capacity per unit areal density of vegetation. This equation is being used in the NCI study for daily rainfall amounts in excess of 5 mm.

Given the importance of the interception coefficient in the assessment of the ^{131}I exposures, and the limited information on its value under conditions of moderate or heavy rainfall, a research program was designed to investigate the dependence of the mass interception coefficient on the nature and physico-chemical form of radionuclides, the rainfall amount and intensity, and the type and height of vegetation. The results of these experiments, when radionuclides on particulate form were used, are in general agreement with those derived from the model. For ^{131}I in soluble form, however, the experimental values of the mass interception coefficient are about 10 times lower than those predicted by the model.

TS.3.2. Effective half-time of retention of ^{131}I by vegetation

After ^{131}I is deposited on vegetation, environmental removal processes combine with radioactive decay to reduce the initial amount on the vegetation surface. The time necessary for one-half of the activity to be removed by environmental processes is referred to as the environmental half-time (T_w). This time value, together with the radioactive half-life (T_r) determines the effective half-time (T_{eff}):

$$T_{eff} = \frac{T_w \times T_r}{T_w + T_r} \tag{6}$$

Values of T_w may be expected to vary markedly as a function of the growth of vegetation and of meteorological conditions. Given the short radioactive half-life of ^{131}I, however, the effective half-time T_{eff} is not particularly sensitive to large variations of the environmental half-time T_w. The average value of T_w was assumed to be 14 d, yielding an effective half-time T_{eff} of slightly more than 5 d.

TS.3.3. Pasture intake by dairy cows

Fresh pasture is that portion of the cow's diet that is of concern in this study because it is the only dietary component that usually is directly exposed to fallout, and can be contaminated by short-lived ^{131}I to a significant extent.

It would not be appropriate to use information regarding current dairy practices as a surrogate for dairy practices during the 1950s. The trend towards larger farms, together with the greater daily feed intake required by higher milk producing cows, has led to the increased use of drylot feeding which utilizes little or no pasture.

The only nationwide standardized information source for dairy herd diets is the Dairy Herd Improvement Association (DHIA). The annual summaries of some of the data collected for the herds included in the DHIA program were obtained from the Animal Improvement Program Laboratory, which has maintained since 1953 a national computer database of the DHIA records. Using this database, the pasture intake by dairy cows has been calculated in two steps: (1) estimation of the total daily dry matter intake of dairy cows, averaged over the years 1953 to 1963, for each of the contiguous states, and (2) estimation of the fraction of total dry matter intake that was provided by pasture.

TS.3.3.1. Total daily dry matter intake of dairy cows

Feeding standards have been established to help farmers in selecting the properly balanced rations for optimum health of their animals and maximum milk production. The maximum daily intake DM, expressed in terms of dry matter (kg), is estimated using the methodology proposed by the National Research Council, as a function of the cow's body weight (BWT) and of the percentage of cow's body weight to be fed to the cow per day (PBWT):

$$DM = \frac{BWT \times PBWT}{100} \tag{7}$$

Values of PBWT are estimated as a function of the cow's body weight and of the daily production of milk normalized to 4% fat content, FCM. The values of FCM, expressed in kg d^{-1}, vary with the milk yield, MY (kg d^{-1}), and with the fat yield, FAT (kg d^{-1}), according to:

$$FCM = [0.4 \times MY] + [15 \times FAT] \tag{8}$$

The annual herd averages for cow's body weight, milk yield, and fat yield from each state that were reported to the DHIA during the time period from 1953 to 1963 were used to calculate the average total dry matter intake for the dairy cows in each state.

TS.3.3.2. Fraction of total dry matter intake from pasture

The fraction of the total daily dry matter intake by cows which is obtained from pasture in each state has been estimated on a weekly basis using the expert opinions of individual United States Department of Agriculture (USDA) Extension Specialists across the country and of other knowledgeable persons, who were asked to help reconstruct pasture feeding practices during the 1950s. Although subjective, these estimates are the best obtainable information on the seasonal variation of pasture practices at that time. In some states, the environmental conditions, and therefore the pasture practices, varied considerably across the state. To take this into account, more than one pasture region was assigned to the states of Alabama, Arizona, California, Georgia, Mississippi, North Carolina, South Carolina, Texas, and Utah. A total of 70 pasture regions have been defined for each contiguous U.S.

The daily dry matter intake by cows which was obtained from pasture $PI_{w,s}$ (kg d^{-1}) during a given week w in a given pasture region s (usually consisting of an entire state) was calculated as the product of total dry matter intake in the pasture region s, DM_s (kg d^{-1}), and of the fraction of the diet from pasture during week w in the pasture region s, $FP_{w,s}$:

$$PI_{w,s} = DM_s \times FP_{w,s} \tag{9}$$

For each pasture region, a pasture intake estimate is provided in the report for each week of the year.

TS.3.4. Intake-to-milk transfer coefficient

The intake-to-milk transfer coefficient for ^{131}I and for cows, f_m (d L^{-1}), is the time-integrated concentration of ^{131}I in milk (nCi d L^{-1}) per unit of ^{131}I activity consumed by the cow (nCi). This transfer coefficient has been determined experimentally in a large number of studies, including tracer experiments with stable or radioactive iodine and field studies in which pasture was contaminated by ^{131}I resulting from releases from nuclear facilities or from fallout from nuclear weapons tests. Reported literature values range from 2×10^{-3} to 4×10^{-2} d L^{-1} but it seems that fallout studies yielded values in the lower part of the range. For the purposes of this report, it is assumed that the average value of f_m for ^{131}I and for cows is 4×10^{-3} d L^{-1}.

TS.4. ESTIMATION OF THE ^{131}I ACTIVITIES INGESTED BY PEOPLE

Once the time-integrated ^{131}I concentrations in fresh cow's milk produced in any county of the U.S. have been estimated from equation 1, it is necessary to determine how much milk was produced and where it was consumed in order to derive the time-integrated ^{131}I concentrations in the milk consumed by man and the corresponding ^{131}I intakes. Accordingly, information is needed on the milk production in each county, on the milk distribution pattern within each county and each state, on the delay between production and consumption of milk, and on the consumption of milk as a function of factors such as race, age, and sex.

TS.4.1. Milk production

The production of milk in a given county in the 1950s was estimated from county data on th number of cows C_c published by the U.S. Department of Commerce in the 1954 Census of Agriculture combined with state statistics on the average annual milk production per cow CP_s published by the U.S. Department of Agriculture. Assuming that the average milk production per cow reported for the state did not vary significantly from the average milk production rate in any county in the same state, the total annual production of milk in a given county MP_c was estimated as:

$$MP_c = C_c \times CP_s \tag{10}$$

The subscript c for all variables in this equation, as well as in the following ones, denotes the value for a given county while the subscript s denotes the value for a given state.

TS.4.2. Milk utilization

The amount of milk produced in any county c of the contiguous United States that is available for fluid use $TMFU_c$ is estimated by subtracting the amount of milk used on farms for feeding calves and butter production MUF_c, and the milk used to manufacture dairy products MM_c from the total amount of milk produced MP_c:

$$TMFU_c = MP_c - MUF_c - MM_c \tag{11}$$

The amount of milk that is used on farms for feeding calves and for butter production MUF_c (referred to as "milk used on farm" in this paper) in a given county c is estimated by apportioning the state value for the milk used on farms MUF_s, as reported by USDA according to the number of cows in each county:

$$MUF_c = \frac{MUF_s \times C_c}{C_s} \tag{12}$$

The total amount of milk used in each state for the manufacture of dairy products MM_S is reported by the USDA but data for each county are not available. Since milk for fluid use would have brought a higher price, it can be assumed that only the surplus, after the fluid needs of the population of that county had been met, would have been sold, at a lower price, to manufacturing plants. To estimate the milk used for manufacture of dairy products in each county, it is assumed that in counties where more milk was produced than was needed for fluid use in that county, a portion of the milk produced was purchased by a manufacturing plant (located in that county or near-by). The amount of milk used, in each county with a milk surplus, for the manufacture of dairy products is estimated using the value for the state, MM_S, and apportioning it between the surplus counties, for which the total milk production is denoted as TMP_S, according to the total amount of milk produced in that county, MP_C:

$$MM_C = \frac{MM_S \times MP_C}{TMP_S} \qquad (13)$$

Estimates of annual volumes of milk available for fluid use in each county of the contiguous U.S. in the 1950s are provided in the report.

TS.4.3. Milk distribution

The volume of milk available for fluid use estimated by this model is either consumed on the farm, distributed for consumption to the local county population, or distributed to areas outside the county where the amount of available milk does not meet the consumption needs of the population. The distribution of milk to other counties usually results in the mixing of milk from a number of sources that may have varying ^{131}I concentrations as a result of differences in fallout deposition.

Milk, in general, was produced close to the population centers that required the milk supply, but the increasing use of refrigerated tank cars and the reduced cost of transportation also made it possible to ship milk to greater distances to satisfy major urban areas and to fulfill emergency shortages.

Information on volumes and directions of milk distribution and on the delay times between production and consumption is, in general, more qualitative than quantitative. Although relevant data have been published for federally administered Milk Marketing Orders and for parts of the west, they do not provide all of the information required in this study and cannot be used to derive values for the entire country. It was therefore decided to resort to a simple model based on the nationwide statistics on milk production and utilization reported by the U.S. Department of Commerce and the U.S. Department of Agriculture, and to validate as much as possible the structure of the model and the assumptions used by means of published information and recollections of experts. Given the uncertainties included in the assessment, it was deemed sufficient to derive only one model of milk distribution for the 1950s and to use the 1954 data for that purpose.

In this model, the total milk for fluid use in a county ($TMFU_c$) is divided into four categories corresponding to the consumption of milk by following population groups:

- category 1 : those living on the farms of the county where the milk was produced;
- category 2 : those living in the county where the milk was produced but not on farms;

- category 3 : those living in a group of neighboring counties within a designated "region", or group of neighboring counties in a state, and
- category 4 : those living at greater distances, that is, in other "regions" in the same or another state.

The model assumes that the milk produced in a county was used initially to satisfy the consumption needs within that county and, if there was a surplus, to fulfill the needs that had not been satisfied elsewhere.

The consumption of milk of category 1 in a given county, MCF_c, was assumed to occur with a delay of one day following its production by the cow and to be proportional to the number of farms in that county, F_c:

$$MCF_c = \frac{MCF_s \times F_c}{F_s} \qquad (14)$$

The volume and source of milk in category 2, milk consumed in county but not on farms, is dependent on the amount of milk available in the county. The expected milk consumption in the county EC_c was subtracted from the total volume of milk for fluid use available in the county $TMFU_c$; the result indicates whether the balance of milk MB_c in the county was surplus or deficit:

$$MB_c = TMFU_c - EC_c \qquad (15)$$

According to whether MB_c is positive or negative, milk is exported to, or imported from, other counties. Milk in category 2 is assigned a delay time of 2 d between production and consumption.

To simulate the flow of milk over short distances, neighboring counties have been grouped together into "regions". The geographic extent of the regions are based on the Crop Reporting Regions and milkshed areas outlined by each state's Department of Agriculture. Additional regions were drawn to isolate the population concentrated around cities in each state. For the states close to the NTS (Nevada, Arizona, Utah and part of California), available information on milk distribution and pasture practices were used to designate boundaries of the regions. A total of 429 milk regions have been defined in the contiguous U.S.

The first step used in the model to balance the surplus (or deficit) of milk in an individual county is by flow of milk between counties in the same "region". The volume of milk pooled from the counties with a surplus of milk is distributed to the counties of the region with a deficit of milk, proportionate to their needs. This volume of milk, exported to deficit counties within the region, constitutes the milk of category 3, to which a delay time of 3 d is assigned.

If the volume of the surplus of milk in the region does not cover entirely its needs, additional milk must be provided by another region. Milk of category 4 is that which is imported into a deficit region from another surplus region or, conversely, that which is exported from a surplus region into a deficit region. It is assumed to have a delay time of 4 d between production and consumption because the milk in this category has travelled the furthest distance from producer to consumer. Movements of milk in category 4 between surplus regions and deficit regions were designed to achieve balance between production and consumption at the national level.

The assumptions regarding the direction and distance that milk was distributed during the 1950s are based upon Agricultural Research Stations reports as well as information made available from State Agricultural Department Milk Boards, Federal Milk Marketing Administrators Offices, and

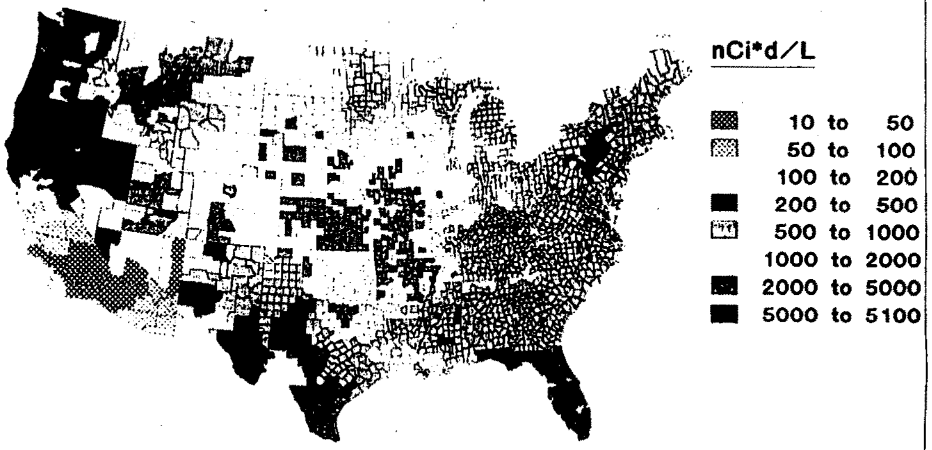
Agricultural Economists with the Extension Service. The overall surplus and deficits calculated for each region of the country, as a result of the needs of major population areas, drive the major patterns of milk flow. The fact that most of the surplus milk in the U.S. was produced in the northern part of the country and shipped south also has an important influence on the distribution patterns chosen.

Estimates of time-integrated concentrations of ^{131}I in each category of fresh cows' milk have been obtained using this methodology for each county of the contiguous U.S. and for each of the 90 tests considered in the report. Figure TS.3 presents the time-integrated concentrations of ^{131}I in volume-weighted milk summed over all tests.

TS.4.4. Activity intakes of ^{131}I by man

The ^{131}I intake from milk by man is the product of the time-integrated concentration of ^{131}I in the milk ingested and of the milk consumption rate. Individual intakes of ^{131}I from milk vary widely from person to person because of variability in such factors as environmental parameters, patterns of milk production and distribution, and dietary habits. Therefore, realistic estimates of individual intakes can be made only if specific information is available on the individual considered (age, sex, place of residence, source of milk, delay between production and consumption of milk, milk consumption rate). In the absence of personal data, only average intakes over large or homogeneous groups of people can be estimated with reasonable accuracy. For this reason, the ^{131}I intakes of milk by man estimated in this report for each county and for each nuclear test are averages over specified population groups deemed to be representative of a large spectrum of individuals. However, the individual ure TS.3.

TIME INTEGRATED CONCENTRATIONS OF I-131 IN VOLUME-WEIGHTED MILK: ALL TESTS



who wishes to estimate his or her own thyroid dose will find in this report all the information necessary do so.

Although ingestion of cows' milk is generally the predominant contributor to the intake of ^{131}I, other exposure routes need to be taken into consideration for individuals who consume little or no cows' milk. These exposure routes, which include inhalation and the ingestion of goat's milk, cottage cheese, leafy vegetables, and eggs, are considered in the report in a much less detailed manner than the ingestion of fresh cows' milk.

TS.5. ESTIMATION OF THE THYROID DOSES FROM ^{131}I

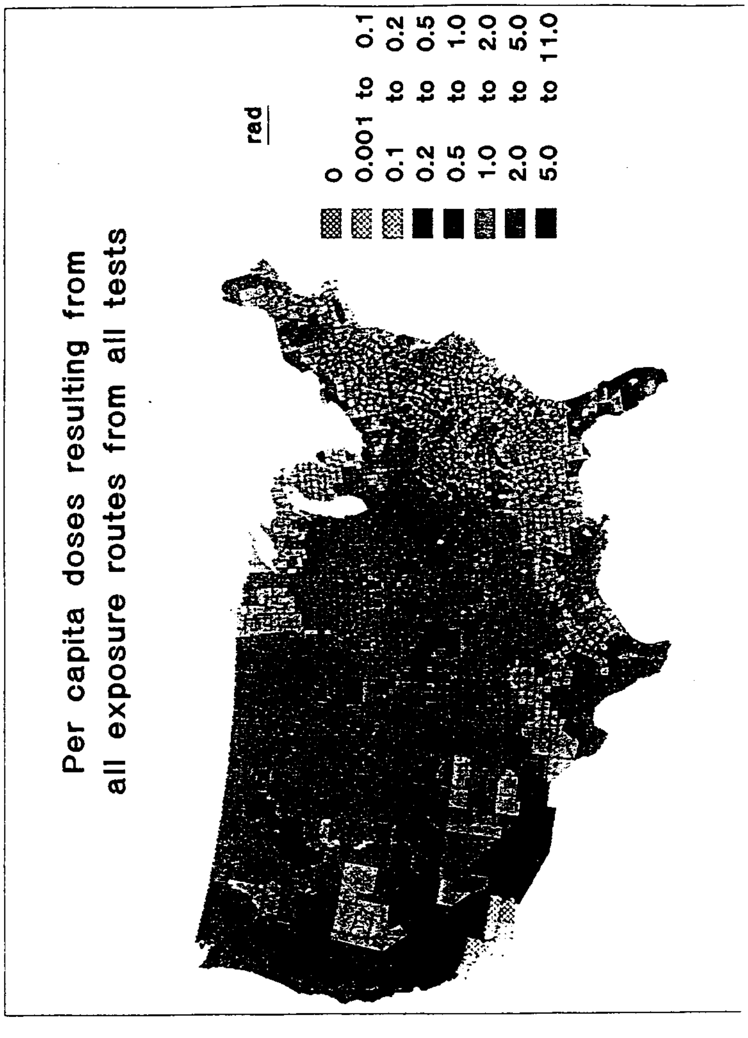
For each test and each county, average thyroid doses from ^{131}I have been estimated for 14 age and sex groups:

- fetus (0-10 wk; 10-20 wk; 20-30 wk; 30-40 wk),
- infant (0-3 mo; 3-6 mo; 6-9 mo; 9-12 mo),
- child (1-4 y; 5-9 y; 10-14 y; 15-19 y)
- adult male,
- adult female.

For each of those age and sex groups, thyroid doses have been assessed for 4 types and amounts of milk consumed:

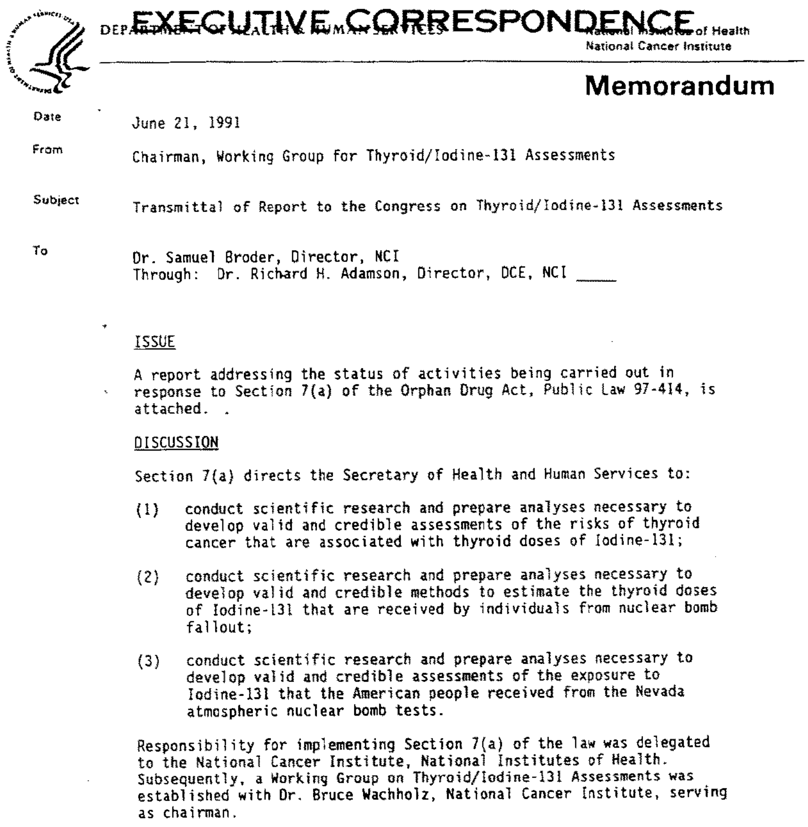
- average consumption rate of milk with the volume-weighted concentration of ^{131}I estimated for the county,
- "high" consumption rate of milk with the highest concentration of ^{131}I estimated for the county,
- "high" consumption rate of milk obtained from backyard cows,
- no consumption of fresh cows' milk.

In addition, the per capita thyroid doses from ^{131}I have been estimated for each test and each county. Figure TS.4 presents the estimated per capita thyroid doses for each county of the contiguous United States summed over all tests. The highest thyroid doses, in the range from 5 to 11 rads, are estimated not only for the stable populations in counties of states close to the NTS, like Nevada and Utah, but also for populations in counties of states relatively far away from the NTS, like Arkansas, Colorado, Idaho, Kansas, Missouri, and Montana. Low thyroid doses, in the range from 0.001 to 0.1 rad, are calculated for counties in southern California. The average per capita thyroid dose from all tests is estimated to have been about 2 rad.


Per capita doses resulting from
all exposure routes from all tests
rad
0
0.001 to 0.1
0.1 to 0.2
0.2 to 0.5
0.5 to 1.0
1.0 to 2.0
2.0 to 5.0
5.0 to 11.0

ATTACHMENT

10



EXECUTIVE CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES
National Institutes of Health
National Cancer Institute

Memorandum

Date June 21, 1991

From Chairman, Working Group for Thyroid/Iodine-131 Assessments

Subject Transmittal of Report to the Congress on Thyroid/Iodine-131 Assessments

To Dr. Samuel Broder, Director, NCI
Through: Dr. Richard H. Adamson, Director, DCE, NCI ____

ISSUE

A report addressing the status of activities being carried out in response to Section 7(a) of the Orphan Drug Act, Public Law 97-414, is attached.

DISCUSSION

Section 7(a) directs the Secretary of Health and Human Services to:

(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear bomb fallout;

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests.

Responsibility for implementing Section 7(a) of the law was delegated to the National Cancer Institute, National Institutes of Health. Subsequently, a Working Group on Thyroid/Iodine-131 Assessments was established with Dr. Bruce Wachholz, National Cancer Institute, serving as chairman.

RECOMMENDATION

That the attached report be approved and forwarded to the Secretary for transmittal to the Congress.

Bruce W. Wachholz, Ph.D.

Attachments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

June 21, 1991

Chairman, Working Group for Thyroid/Iodine-131 Assessments

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DEPARTMENT OF HEALTH & HUMAN SERVICES
National Institutes of Health
National Cancer Institute

Memorandum

Date

From Director, National Cancer Institute

Subject Transmittal of Report to the Congress on Thyroid/Iodine-131 Assessments

To Dr. Bernadine Healy, Director, NIH

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Samuel Broder, M.D.

Attachments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Director, National Cancer Institute

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Attachments

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date

From Director, NIH

Subject Transmittal of Report to the Congress on Thyroid/Iodine-131 Assessments

To Dr. James O. Mason
Assistant Secretary for Health

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(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear bomb fallout;

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests.

Responsibility for implementing Section 7(a) of the law was delegated to the National Cancer Institute, National Institutes of Health. Subsequently, a Working Group on Thyroid/Iodine-131 Assessments was established with Dr. Bruce Wachholz, National Cancer Institute, serving as chairman.

RECOMMENDATION

That the attached report be approved and forwarded to the Secretary for transmittal to the Congress.

Bernadine Healy, M.D.

Attachments

EXECUTIVE CORRESPONDENCE

Need official
memo paper

Assistant Secretary for Health

Transmittal of Report to the Congress o essments
---- ACTION

The Secretary
Through: US ____
COS ____
ES ____

ISSUE

A report addressing the status of activities being carried out in response to Section 7(a) of the Orphan Drug Act, Public Law 97-414, is attached.

DISCUSSION

Section 7(a) directs the Secretary of Health and Human Services to:

(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear bomb fallout;

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests.

Responsibility for implementing Section 7(a) of the law was delegated to the National Cancer Institute, National Institutes of Health. Subsequently, a Working Group on Thyroid/Iodine-131 Assessments was established with Dr. Bruce Wachholz, National Cancer Institute, serving as chairman.

RECOMMENDATION

That the attached report be approved and forwarded to the Secretary for transmittal to the Congress.

James O. Mason, M.D., Dr.P.H.

Attachments:
Tab A - Executive Summary
Tab B - Cost Worksheet
Tab C - Transmittal Letters
Tab D - Report to Congress

Interim Report of the Working Group for Thyroid/Iodine-131 Assessments
Section 7(a) of the Orphan Drug Act, Public Law 97-414

Executive Summary

The Working Group for Thyroid/Iodine-131 Assessments, established by the Director of the National Cancer Institute to assist the Institute and the Secretary of Health and Human Services in discharging Departmental obligations under Public Law 97-414, Section 7(a), together with staff experts engaged for this purpose, are preparing a draft final report on the results of research and analyses to develop valid and credible (1) assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric bomb tests, and (2) methods to estimate the thyroid doses resulting from such exposure. The data base, which includes time- and county-specific estimates of Iodine-131 ground and milk contamination, together with person-specific residence and dietary information as well as age and sex characteristics will provide an individual basis for estimates of Iodine-131 exposure. The availability of sufficient data to permit a valid and credible assessment of the risk of thyroid cancer associated with a thyroid dose of Iodine-131 is not anticipated for at least two years.

The Honorable Dan Quayle
President of the Senate
Washington, DC 20515

Dear Mr. President:

Section 7(a) of the Orphan Drug Act, Public Law 97-414, requires the Secretary of Health and Human Services to conduct research and prepare analyses necessary to: (1) develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131, (2) develop valid and credible methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear bomb fallout, and (3) develop valid and credible assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests.

A final report on items (2) and (3) above is expected during 1992 from the Working Group that was established to assist the Secretary in fulfilling the requirements of Section 7(a) of Public Law 97-414. Availability of adequate credible data to address item (1) above is not anticipated for at least another two years.

The attached status report of activities being carried out in accordance with Public Law 97-414, Section 7(a) is respectfully submitted. The total cost of the preparation of this report is $1500.

Sincerely,

Louis W. Sullivan, M.D.

Enclosure

The Honorable Thomas S. Foley
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Section 7(a) of the Orphan Drug Act, Public Law 97-414, requires the Secretary of Health and Human Services to conduct research and prepare analyses necessary to: (1) develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131, (2) develop valid and credible methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear bomb fallout, and (3) develop valid and credible assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests.

A final report on items (2) and (3) above is expected during 1992 from the Working Group that was established to assist the Secretary in fulfilling the requirements of Section 7(a) of Public Law 97-414. Availability of adequate credible data to address item (1) above is not anticipated for at least another two years.

The attached status report of activities being carried out in accordance with Public Law 97-414, Section 7(a) is respectfully submitted. The total cost of the preparation of this report is $1500.

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Louis W. Sullivan, M.D.

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Interim Report of the Working Group for Thyroid/Iodine-131 Assessments
Section 7(a) of the Orphan Drug Act, Public Law 97-414

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COST WORKSHEET

1. Development Costs:	
A. Cost of Conferences	X
B. Grants	X
C. Contracts	X
D. Consultants	X
E. Travel	X
Subtotal	X
2. Production Costs:	
A. Updating existing Data Files	X
B. Data Analysis	$ 50
C. Editing	$ 200
D. Printing, Duplicating, etc.	$ 250
Subtotal	$ 500
3. Direct Personnel Costs	
Direct Personnel	$1,000
Subtotal	$1,000

Total Costs: $1,500

Interim Report of the Working Group for Thyroid/Iodine-131 Assessments
Section 7(a) of the Orphan Drug Act, Public Law 97-414

The previous Interim Report transmitted in May, 1986, provides the background and objectives of this activity and is incorporated into this report by reference (Enclosure A).

The major efforts anticipated at the time of the earlier report included:

1. The reconstruction of the continental cloud trajectory following each of the atmospheric weapons tests conducted at the Nevada Test Site between 1951 and 1962.

2. The reconstruction of rain patterns occurring during the time of passage of each cloud trajectory.

3. The location, review, and analysis of all relevant monitoring data.

4. The correlation of 1-3 above to estimate deposition of Iodine-131 from fallout by geographical area.

5. The determination of environmental and human nutritional pathways of deposited Iodine-131 to estimate the population exposure from the Iodine-131 in the fallout.

6. The estimation of human thyroid size and activity as a function of sex and age, to assess the radiation dose to the thyroid from ingested Iodine-131.

7. The assessment of the risk of thyroid cancer from a radiation dose of Iodine-131 to the thyroid as a function of sex and age, to the extent feasible.

Technical and analytical activities associated with items 1-6 are complete. The draft final report on these activities is in preparation and should be available for peer review prior to January 1, 1992, on or about which date it is expected to be submitted to the Department. Subsequently it will be transmitted to the Congress. The availability of an adequate data base to address item (7) continues to be elusive. While limited additional information has been presented in recent years that is suggestive, it is of a controversial nature and inadequate as basis for risk assessment. Epidemiology studies to assess the risk of thyroid cancer from exposure to Iodine-131 are long term in nature and have been initiated or expanded and are underway in Sweden, Israel, Yugoslavia, and the United States. Efforts also are underway to interact with the Soviet Union in designing epidemiological studies to investigate the occurrence of thyroid disease, including cancer, among persons exposed to Iodine-131 released as a result of the Chernobyl accident. This latter effort, if successful will result in many years of study, while the former new or expanded studies are not expected to yield useful information for another 2-4 years.

A brief summary of the technical progress regarding the above activities follows:

Meteorological modelling of fallout trajectories at four elevations across the country was carried out for selected atmospheric tests based upon retrieved Weather Service data. These trajectories were compared with precipitation data available from one or more locations in each county in the United States. Precipitation records are of particular importance because the intersection of the fallout cloud and precipitation results in increased deposition of radionuclides with the precipitation.

Comparison of fallout levels calculated by such modelling techniques frequently yielded results which were not consistent with monitoring data, however. For this reason the availability of monitoring data was given precedence over modelling calculations except for those tests where no monitoring data existed. Careful reanalysis of the monitoring data, together with sophisticated use of statistical techniques, allowed interpolation of fallout levels between sites of the monitoring locations so that estimates of fallout deposition in each country of the contiguous United States could be made for all the tests that contributed to such fallout.

Because Iodine is transmitted via the pasture - cow - milk food pathway, data relevant to all of the factors related to milk production, processing, distribution and consumption practices in the 1950s and the 1960s was retrieved from official and unofficial sources. Estimation of the amounts of deposited Iodine-131 to which the American people ultimately were exposed required the retrieval and/or acquisition of data and information in a number of areas: pasture grazing practices of large and family dairy herd operators in various parts of the country, pasture grass consumption needs of dairy cows, milk production by county, use of milk for personal or multiple commercial purposes (e.g. milk, cheese, ice cream), flow of milk into and out of each county and among area counties and milk marketing regions, and milk consumption as a function of age, sex, and region of the country. Moreover, the time over which these events took place and the mixing of milk originating from more or less contaminated areas contributed to the changes in the concentration of Iodine-131 in milk as it moved from the producing cow to the consumer.

Calculation of the radiation dose to the thyroid gland due to Iodine-131 involves estimation of the uptake of radioiodine from the blood, the mass of the thyroid, and the duration of retention in the gland. Average values for the weight of adult child and fetal thyroid glands and variation in uptake of Iodine-131 by the thyroid according to geographic region, time interval, and age (adult, newborn, and fetus) have been characterized in past studies. Doses to the thyroid per microcurie of Iodine-131 in take have been calculated for various age groups.

As a result of these efforts the report will provide the methodology by means of which estimates of exposure to Iodine-131 can be made for persons of different ages of each sex in each county in the United States for every day in which fallout clouds travelled the country following each atmospheric weapons test that resulted in meaningful fallout. From this information, and using the residence and dietary histories of an individual, an estimate can be made of a person's exposure to Iodine-131 on any day in any county. The data to support such an assessment is quite extensive so that the report, together with its supplementary documents, is expected to be of the order of 100,000 pages.

As indicated previously, the information base of the risk of thyroid cancer resulting from exposure to Iodine-131 has not improved substantially in the past few years and the reader is referred to the previous Interim Report (pp 3-4) for discussion of this topic. As also indicated above, current studies are anticipated to last another 2-4 years before a data base might be available. The number of identified persons exposed to known amounts of Iodine-131 and fulfilling the criteria required for productive clinical and/or epidemiological followup studies is limited; hence the need for careful and longterm studies wherever appropriate populations of persons can be located, whether in the United States or in other countries.

In summary, a final report on all aspects of Public Law 97-414 Section 7(a) except for an estimate of the risk of thyroid cancer in persons exposed to Iodine-131 is expected to be transmitted to the Congress in 1992. The possible availability of credible data to provide a risk estimate is not expected for another 2-4 years, and a report addressing this issue will be submitted as soon as the Working Group is of the opinion that it is reasonable and appropriate to provide a valid and credible estimate.

ATTACHMENT

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October 1, 1990- September 31, 1991

Jack Gruber ✓

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Division Of

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U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES

NATIONAL
CANCER
INSTITUTE

ANNUAL REPORT OF

THE RADIATION EFFECTS BRANCH
CHEMICAL AND PHYSICAL CARCINOGENESIS PROGRAM
DIVISION OF CANCER ETIOLOGY
NATIONAL CANCER INSTITUTE

October 1, 1990 through September 30, 1991

The Radiation Effects Branch (REB), established in response to Public Law 95-622, plans, directs and administers a program consisting of grants and contracts investigating the means by which exposure to ionizing and non-ionizing radiations, particularly at low doses or dose rates, leads to molecular and cellular events and processes resulting in mutagenesis, cell transformation, and carcinogenesis, and the associated dose-effect relationships; directs and administers selected epidemiological studies investigating the effects of radiation exposure in humans; provides a broad spectrum of information, advice, and consultation to scientists and to institutional science management officials relative to the National Institutes of Health (NIH) and the National Cancer Institute (NCI) funding and scientific review policies and procedures, preparation of grant applications, and choice of funding instruments; maintains contact with other Federal agencies and institutions and with the broader relevant scientific community to identify new and needed research in, and related to, the fields of radiation mechanisms and effects; provides NCI management with recommendations concerning funding needs, priorities, and strategies for the support of relevant research areas consistent with the current state of development of individual research elements and the promise of new initiatives; provides information, advice, and guidance to NCI management and staff on radiation-related issues; implements the mandates of Public Law 97-414, Section 7(a); and represents the Department of Health and Human Services on the Science Panel of the Committee on Interagency Radiation Research and Policy Coordination, which is located within the Office of Science and Technology Policy, Office of the President.

The extramural activities of the Branch are accomplished through contractual agreements with universities and other Federal agencies, and through traditional individual research grants (R01), conference grants (R13), first independent research support and transition (FIRST) awards (R29), program project grants (P01), small business innovative research (SBIR) grants (R43/44), outstanding investigator grant (OIG) awards (R35), methods to extend research in time (MERIT) awards (R37), and academic research enhancement awards (AREA) (R15). At present the Branch administers 110 extramural research activities with an annual budget of 19 million dollars (Tables I and II). The program consists of two broad categories of research: mechanisms of radiation damage and repair, and radiation carcinogenesis. In addition, the NIH and the NCI have assigned to the Branch responsibility for the implementation of sections of two Public Laws addressing radiation-related issues emanating from Congressional policy concerns.

Section 7(a) of Public Law 97-414, the Orphan Drug Act, requires the Secretary to conduct scientific research and prepare analyses necessary to develop valid and credible (1) assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131, (2) methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear weapons fallout, and (3) assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests conducted during the years 1951-1963. A working committee consisting of relevant expertise within and outside of the government is addressing these issues. The committee is organized into three task groups addressing the risk of thyroid cancer per unit dose of Iodine-131 to the thyroid, the dose of Iodine-131 to the thyroid per unit of exposure to Iodine-131, and the development and verification of models to estimate the exposure of the American people to Iodine-131 resulting from radioactive fallout associated with atmospheric nuclear weapons tests at the Nevada Test Site. Extensive efforts have been expended in the identification, recovery, acquistion and analyses of a wide range of data relevant to the required exposure and dose reassessments; these efforts have been carried out with the assistance of staff expertise acquired for this purpose and via interagency agreements. Activities associated with items (2) and (3) above should be complete during the next reporting period, with final reports to be submitted thereafter.

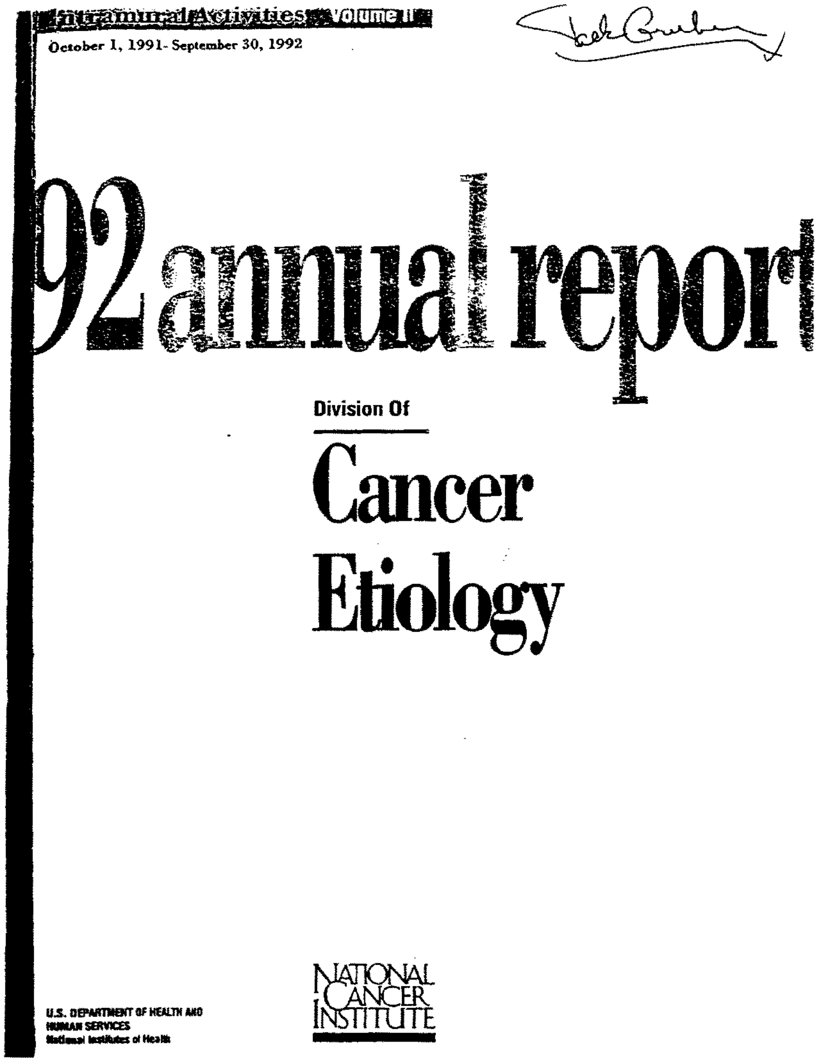
Reviews and analyses of fallout source terms and available monitoring data for each of the atmospheric tests have been completed. In addition, meteorological conditions at multiple altitudes at the time of each test, together with wind and precipitation patterns across the United States during the days the fallout cloud was over United States territory, have been reconstructed. These data form the bases upon which statistical interpolation and extrapolation of fallout levels (i.e., ground surface levels) of Iodine-131 have been made for each of the then-existent 3,071 counties within the continental United States for each of the tests.

Since the primary exposure of the public to Iodine-131 following the tests was via the consumption of milk produced by grazing cows, milk production and distribution patterns, by county, were reconstructed. This methodology resulted in estimates of Iodine-131 concentrations in milk in each county and included the consideration of such factors as the location and times of the year when dairy herds were on pasture in relation to the date of each test and the areas from which milk was mixed. These estimated Iodine-131 concentrations in milk, combined with demographic information and individual consumption rates, will permit an estimate of Iodine-131 exposure for residents of each county as a function of age and sex. It is anticipated that the exposure estimates will be completed within a year.

The Mechanisms of Radiation Damage and Repair Program includes, but is not limited to, studies on molecular and cellular changes resulting from exposure to ionizing and non-ionizing (principally ultraviolet [UV]) radiation, DNA damage and repair following radiation exposure, the hypermutability, mutagenesis, and malignant transformation of exposed cells, mechanisms of tumor promotion, and mutagenicity-carcinogenicity relationships following exposure to radiation.

The Radiation Carcinogenesis Program addresses the effects of exposure to ionizing and non-ionizing (principally UV) radiation, including, for example, the role of oncogenes, the identification of molecular markers unique to cells transformed by radiation, the role of cofactors and systemic mediators in radiation-induced carcinogenesis, the effect of dose rate and linear energy transfer on radiation-induced effects, dose-effect relationships, interspecies comparisons, cocarcinogenesis, the incidence of selected diseases as they may relate to exposure from radioactive fallout, and synthesis of radiobiological data in the assessment of risk and the establishment of appropriate radiation protection practices.

Research activities are concerned with a wide variety of radiation effects including mechanisms of damage and repair of DNA by ionizing and non-ionizing radiation, and radiation carcinogenesis. The majority of the 108 grants (77) support investigations relating to mechanisms of radiation damage and repair of cellular DNA, 60 of which investigate the effects of exposure to ionizing radiation and 17 of which study the consequences of exposure to ultraviolet radiation, microwaves and ultrasound. Twenty-four grants and two contracts fund studies in radiation carcinogenesis; research addressing radiation risks and the compilation and assessment of information is the objective of six grants. A Request for Applications (RFA) entitled "Molecular Analyses of Radiation-Induced Genetic Damage" was issued in response to guidance received during a workshop held earlier on the same topic. Twenty-four proposals were submitted in response to the RFA.



Intramural Activities Volume II

October 1, 1991- September 30, 1992

Jack Gruber

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U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES
National Institutes of Health

NATIONAL
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The extramural activities of the Branch are accomplished through contractual agreements with universities and other Federal agencies, and through traditional individual research grants (R01), conference grants (R13), first independent research support and transition (FIRST) awards (R29), program project grants (P01), small business innovative research (SBIR) grants (R43/44), outstanding investigator grant (OIG) awards (R35), methods to extend research in time (MERIT) awards (R37), and academic research enhancement awards (AREA) (R15). At present the Branch administers 122 extramural research activities with an annual budget of 22.7 million dollars (Tables I and II). The program consists of two broad categories of research: mechanisms of radiation damage and repair, and radiation carcinogenesis. In addition, the NIH and the NCI have assigned to the Branch responsibility for the implementation of a section of a Public Law addressing radiation-related issues emanating from congressional policy concerns.

Section 7(a) of Public Law 97-414, the Orphan Drug Act, requires the Secretary to conduct scientific research and prepare analyses necessary to develop valid and credible (1) assessments of the risks of thyroid cancer that are associated with

thyroid doses of Iodine-131, (2) methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear weapons fallout, and (3) assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests conducted during the years 1951-1963. A working committee consisting of relevant expertise within and outside of the government is addressing these issues. The committee is organized into three task groups addressing the risk of thyroid cancer per unit dose of Iodine-131 to the thyroid, the dose of Iodine-131 to the thyroid per unit of exposure to Iodine-131, and the development and verification of models to estimate the exposure of the American people to Iodine-131 resulting from radioactive fallout associated with atmospheric nuclear weapons tests at the Nevada Test Site. Extensive efforts have been expended in the identification, recovery, acquisition and analyses of a wide range of data relevant to the required exposure and dose reassessments; these efforts have been carried out with the assistance of staff expertise acquired for this purpose and via interagency agreements. Activities associated with items (2) and (3) above have been completed during the present reporting period, and final reports will be submitted during the next reporting period.

Reviews and analyses of fallout source terms and available monitoring data for each of the atmospheric tests have been completed. In addition, meteorological conditions at multiple altitudes at the time of each test, together with wind and precipitation patterns across the United States during the days the fallout cloud was over United States territory, have been reconstructed. These data form the bases upon which statistical interpolation and extrapolation of fallout levels (i.e., ground surface levels) of Iodine-131 have been made for each of the then-existent 3,071 counties within the continental United States for each of the tests.

Since the primary exposure of the public to Iodine-131 following the tests was via the consumption of milk produced by grazing cows, milk production and distribution patterns, by county, were reconstructed. This methodology resulted in estimates of Iodine-131 concentrations in milk in each county and included the consideration of such factors as the location and times of the year when dairy herds were on pasture in relation to the date of each test and the areas from which milk was mixed. These estimated Iodine-131 concentrations in milk, combined with demographic information and individual consumption rates, permit an estimate of Iodine-131 exposure for residents of each county as a function of age and sex. These exposure estimates have been completed.

The Mechanisms of Radiation Damage and Repair Program includes, but is not limited to, studies on molecular and cellular changes resulting from exposure to ionizing and non-ionizing, principally ultraviolet (UV) radiation, DNA damage and repair following radiation exposure, mutagenesis including radiation-induced hypermutability and genetic instability, malignant transformation by ionizing and non-ionizing radiation, mechanisms of tumor promotion and progression, and mutagenicity-carcinogenicity relationships following exposure to radiation.

The Radiation Carcinogenesis Program addresses the effects of exposure of animal and human cells to ionizing and non-ionizing (principally UV) irradiation. Basic areas of current interest include analyses of genes and gene transcripts showing altered expression in mammalian cells exposed to ionizing radiation, the characterization and elucidation of radiation-associated oncogenes and tumor suppressor genes, and the detection and validation of molecular markers that may be unique to mammalian cells transformed by the various forms of radiation. Several research projects make sophisticated use of animal models combined with molecular and cellular measurements to study specific types of radiation-induced cancer (e.g., breast, leukemia), complex systemic effects such as the detection and analysis of stem-cell populations sensitive to ionizing radiation, the role of hormones on susceptibility to radiogenic cancer, and the influence of ionizing radiation on metastasis. Other areas of research in radiation biology important to REB include radiation quality and dose-effect relationships of ionizing radiation on neoplastic transformation, interspecies comparisons of incidence and types of radiation-induced cancer, and cocarcinogenesis studies. The emphasis in this program increasingly is toward a molecular-level and mechanistic description of the classic radiological endpoints such as radiation-induced cell cycle delay, mutagenesis and neoplastic transformation. The incidence of selected diseases as they may relate to exposure from radioactive fallout, the synthesis of radiobiological data in the assessment of risk, and the establishment of appropriate radiation protection practices continue as important activities supported by the REB.

Research activities in these programs are concerned with a wide variety of radiation effects including mechanisms of damage and repair of DNA by ionizing and non-ionizing radiation, and radiation carcinogenesis. The majority of the 120 grants (83) support investigations relating to mechanisms of radiation damage and repair of cellular DNA, 59 of which investigate the effects of exposure to ionizing radiation and 24 of which study the consequences of exposure to ultraviolet radiation, microwaves or ultrasound. Thirty-one grants and two contracts fund studies in radiation carcinogenesis ranging from those which investigate basic research on mechanisms to those that address radiation risks and the compilation and assessment of information relevant to risk assessment. Six grants were funded (out of 33 received) in response to a previously issued Request for Applications (RFA) entitled, "Molecular Analyses of Radiation-Induced Genetic Damage." Two workshops were held; the subjects of these were "The Function, Regulation and Specificity of Proteins Induced in Cells Exposed to Ionizing Radiation," and "Molecular Mechanisms of Electromagnetic Field (EMF) Induced Transformation in Mammalian Cells."

[illegible] Volume II
October 1, 1992- September 30, 1993

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RADIATION EFFECTS BRANCH
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Section 7(a) of Public Law 97-414, the Orphan Drug Act, requires the Secretary to conduct scientific research and prepare analyses necessary to develop valid and credible (1) assessments of the risks of thyroid cancer that are associated with

thyroid doses of Iodine-131, (2) methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear weapons fallout, and (3) assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests conducted during the years 1951-1963. A working committee consisting of relevant expertise within and outside of the government is addressing these issues. The committee has addressed three tasks: the risk of thyroid cancer per unit dose of Iodine-131 to the thyroid, the dose of Iodine-131 to the thyroid per unit of exposure to Iodine-131, and the development and verification of models to estimate the exposure of the American people to Iodine-131 resulting from radioactive fallout associated with atmospheric nuclear weapons tests at the Nevada Test Site. Extensive efforts have been expended in the identification, recovery, acquisition and analyses of a wide range of data relevant to the required exposure and dose reassessments; these efforts have been carried out with the assistance of staff expertise acquired for this purpose and via interagency agreements. Activities associated with items (2) and (3) above been completed during the present reporting period, and a final report has been prepared.

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Since the primary exposure of the public to Iodine-131 following the tests was via the consumption of milk produced by grazing cows, milk production and distribution patterns, by county, were reconstructed. This methodology resulted in estimates of Iodine-131 concentrations in milk in each county and included the consideration of such factors as the location and times of the year when dairy herds were on pasture in relation to the date of each test and the areas from which milk was mixed. These estimated Iodine-131 concentrations in milk, combined with demographic information and individual consumption rates, permit an estimate of Iodine-131 exposure for residents of each county as a function of age and sex. These exposure estimates have been completed.

Under the auspices of agreements between the United States and Belarus, Russia and Ukraine for studies related to Civilian Nuclear Reactor Safety, the NCI and the REB, together with other components of the NIH, at the request of and under an Interagency Agreement with the Department of Energy, have been working with the Ministries of Health of each of the three countries, and with appropriate institutes and centers within the Ministries, to develop and implement, as appropriate, joint long-term studies of thyroid disease, especially cancer, among children exposed to radioisotopes of iodine as a result of the Chernobyl nuclear power plant accident, and of leukemia among the clean-up workers. A case-control study of 119 children in Belarus with thyroid cancer was begun, including the review of medical and pathology records, identification and selection of control subjects, and initial efforts to reconstruct radiation doses to the thyroid (using techniques similar to those in the above paragraph) of all subjects. Following two years of discussions with Belarussian authorities, scientists and physicians, a prospective cohort study, including individual dose reconstruction, to identify and follow a large number of children in Belarus for thyroid cancer was agreed upon; this research protocol currently is undergoing review in both countries. Similar studies are being discussed with authorities, scientists and physicians in Ukraine; efforts also are being made there to initiate a case-control study of thyroid cancer among children and to reach agreement in the near future on a research protocol for a long-term cohort study on thyroid disease among children. Discussions with Russian authorities also are underway. These activities are coordinated with the Departments of State and Energy and, as appropriate, other U.S. entities (e.g., embassies, Nuclear Regulatory Commission, private organizations) and international organizations (e.g., Commission of the European Communities, World Health Organization).

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Research activities in these programs are concerned with a wide variety of radiation effects including mechanisms of damage and repair of DNA by ionizing and non-ionizing radiation, and radiation carcinogenesis. The majority of the 120 grants (91) support investigations relating to mechanisms of radiation damage and repair of cellular DNA, 65 of which investigate the effects of exposure to ionizing radiation and 26 of which study the consequences of exposure to ultraviolet radiation. Thirty-three grants and two contracts fund studies in radiation carcinogenesis ranging from those which investigate basic research on mechanisms to those that address radiation risks and the compilation and assessment of information relevant to risk assessment.

Volume II

October 1, 1993 - September 30, 1994

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Division Of

Cancer Etiology

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

ANNUAL REPORT OF

RADIATION EFFECTS BRANCH
CHEMICAL AND PHYSICAL CARCINOGENESIS PROGRAM
DIVISION OF CANCER ETIOLOGY
NATIONAL CANCER INSTITUTE

October 1, 1993 through September 30, 1994

The Radiation Effects Branch (REB), established in response to Public Law 95-622, plans, directs and administers a program consisting of grants and contracts investigating the means by which exposure to ionizing and non-ionizing radiations, particularly at low doses or dose rates, leads to molecular and cellular events and processes resulting in mutagenesis, cell transformation, carcinogenesis, and the associated dose-effect relationships; directs and administers selected epidemiological studies investigating the effects of radiation exposure in humans; provides a broad spectrum of information, advice, and consultation to scientists and to institutional science management officials relative to the National Institutes of Health (NIH) and the National Cancer Institute (NCI) funding and scientific review policies and procedures, preparation of grant applications, and choice of funding instruments; maintains contact with other Federal agencies and institutions and with the broader relevant scientific community to identify new and needed research in, and related to, the fields of radiation mechanisms and effects; provides NCI management with recommendations concerning funding needs, priorities, and strategies for the support of relevant research areas consistent with the current state of development of individual research elements and the promise of new initiatives; provides information, advice, and guidance to NCI management and staff on radiation-related issues; implements the mandates of Public Law 97-414, Section 7(a); implements an Interagency Agreement with the Department of Energy under which negotiations with the governments of Belarus, Russia and Ukraine are in process to develop and implement cooperative long-term health studies of thyroid disease in children and leukemia in clean-up workers as they may relate to radiation exposure resulting from the Chernobyl nuclear power plant accident; and represents the Department of Health and Human Services on the Science Panel of the Committee on Interagency Radiation Research and Policy Coordination, which is located within the Office of Science and Technology Policy, Office of the President.

The extramural activities of the Branch are accomplished through contractual agreements with universities and other Federal agencies, and through traditional individual research grants (R01), conference grants (R13), First Independent Research Support and Transition (FIRST) Awards (R29), program project grants (P01), Small Business Innovative Research (SBIR) grants (R43/44), Outstanding Investigator Grant (OIG) Awards (R35), Methods to Extend Research in Time (MERIT) Awards (R37), and Academic Research Enhancement Awards (AREA) (R15). At present the Branch administers 120 extramural research activities with an annual budget of 22.6 million dollars (Tables I and II). The program consists of two broad categories of research: mechanisms of radiation damage and repair, and radiation carcinogenesis. In addition, the NIH and the NCI have assigned to the Branch responsibility for the implementation of a section of a Public Law addressing radiation-related issues emanating from congressional policy concerns.

Section 7(a) of Public Law 97-414, the Orphan Drug Act, requires the Secretary to conduct scientific research and prepare analyses necessary to develop valid and credible (1) assessments of the risks of thyroid cancer that are associated with

thyroid doses of Iodine-131. (2) methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear weapons fallout. and (3) assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests conducted during the years 1951-1963. A working committee consisting of relevant expertise within and outside of the government is addressing these issues. The committee has addressed three tasks: the risk of thyroid cancer per unit dose of Iodine-131 to the thyroid. the dose of Iodine-131 to the thyroid per unit of exposure to Iodine-131. and the development and verification of models to estimate the exposure of the American people to Iodine-131 resulting from radioactive fallout associated with atmospheric nuclear weapons tests at the Nevada Test Site. Extensive efforts have been expended in the identification. recovery. acquisition and analyses of a wide range of data relevant to the required exposure and dose reassessments: these efforts have been carried out with the assistance of staff expertise acquired for this purpose and via interagency agreements. Activities associated with items (2) and (3) above been completed during the present reporting period. and a final report has been reviewed prior to printing. Item (1) is closely related to the thyroid studies in the republics of the former Soviet Union indicated above and discussed below.

Reviews and analyses of fallout source terms and available monitoring data for each of the atmospheric tests have been completed. In addition. meteorological conditions at multiple altitudes at the time of each test. together with wind and precipitation patterns across the United States during the days the fallout cloud was over United States territory. have been reconstructed. These data form the bases upon which statistical interpolation and extrapolation of fallout levels (i.e.. ground surface levels) of Iodine-131 have been made for each of the then-existent 3.071 counties within the continental United States for each of the tests.

Since the primary exposure of the public to Iodine-131 following the tests was via the consumption of milk produced by grazing cows. milk production and distribution patterns. by county. were reconstructed. This methodology resulted in estimates of Iodine-131 concentrations in milk in each county and included the consideration of such factors as the location and times of the year when dairy herds were on pasture in relation to the date of each test and the areas from which milk was mixed. These estimated Iodine-131 concentrations in milk. combined with demographic information and individual consumption rates. permit an estimate of Iodine-131 exposure for residents of each county as a function of age and sex. These exposure estimates have been completed.

Under the auspices of agreements between the United States and Belarus. Russia and Ukraine for studies related to Civilian Nuclear Reactor Safety. the NCI and the REB. together with other components of the NIH. at the request of and under an Interagency Agreement with the Department of Energy. have been working with the Ministries of Health of each of the three countries. and with appropriate institutes and centers within the Ministries. to develop and implement. as appropriate. joint long-term studies of thyroid disease. especially cancer. among children exposed to radioisotopes of iodine as a result of the Chernobyl nuclear power plant accident. and of leukemia among the clean-up workers. A case-control study of 119 children in Belarus with thyroid cancer is nearly complete. including the review of medical and pathology records. identification and selection of control subjects. and initial efforts to reconstruct radiation doses to the thyroid (using techniques similar to those in the above paragraph) of all subjects. Following two years of discussions with Belarussian authorities. scientists and physicians. a prospective cohort study. including individual dose reconstruction. to identify and follow approximately

15,000 children in Belarus for thyroid cancer was agreed upon; this research protocol has been approved by a scientific peer-review committee, by Institutional Review Boards (IRB) in both countries, and by the Office of Protection from Research Risks of the National Institutes of Health. An agreement to implement these studies was signed by the Minister of Health, Belarus and the Department of Energy, and joint implementation activities were begun. Similar studies are being discussed with authorities, scientists and physicians in Ukraine. Efforts also are being made there to initiate a case-control study of thyroid cancer among children, and a research protocol for a long-term cohort study on thyroid disease among children in Ukraine has been agreed upon and has been peer reviewed. It is expected that the protocol will be submitted to IRBs in both countries in the near future. Discussions with Russian authorities also are underway. These activities are coordinated with the Departments of State and Energy and, as appropriate, other U.S. entities (e.g., U.S. embassies, Nuclear Regulatory Commission, private organizations) and international organizations (e.g., Commission of the European Communities, World Health Organization).

The Mechanisms of Radiation Damage and Repair Program includes, but is not limited to, studies on molecular and cellular changes resulting from exposure to ionizing and non-ionizing, principally ultraviolet (UV), radiation, DNA damage and repair following radiation exposure, mutagenesis including radiation-induced hypermutability and genetic instability, malignant transformation by ionizing and non-ionizing radiation, mechanisms of tumor promotion and progression, and mutagenicity-carcinogenicity relationships following exposure to radiation.

The Radiation Carcinogenesis Program addresses the effects of exposure of animal and human cells to ionizing and non-ionizing (principally UV) irradiation. Basic areas of current interest include analyses of genes and gene transcripts showing altered expression in mammalian cells exposed to ionizing radiation, the characterization and elucidation of radiation-associated oncogenes and tumor suppressor genes, and the detection and validation of molecular markers that may be unique to mammalian cells transformed by the various forms of radiation. Several research projects make sophisticated use of animal models combined with molecular and cellular measurements to study specific types of radiation-induced cancer (e.g., breast, leukemia), complex systemic effects such as the detection and analysis of stem-cell populations sensitive to ionizing radiation, the role of hormones on susceptibility to radiogenic cancer, and the influence of ionizing radiation on metastasis. Other areas of research in radiation biology include radiation quality and dose-effect relationships of ionizing radiation on neoplastic transformation, interspecies comparisons of incidence and types of radiation-induced cancer, and cocarcinogenesis studies. The emphasis in this program increasingly is toward a molecular-level and mechanistic description of the classic radiological endpoints such as radiation-induced cell cycle delay, mutagenesis and neoplastic transformation. The incidence of selected diseases as they may relate to exposure from radioactive fallout, the analyses of radiobiological data in the assessment of risk, and the scientific basis for the establishment of appropriate radiation protection practices continue as important activities supported by the REB.

Research activities in these programs are concerned with a wide variety of radiation effects including mechanisms of damage and repair of DNA by ionizing and non-ionizing radiation, and radiation carcinogenesis. The majority of the 120 grants (91) support investigations relating to mechanisms of radiation damage and repair of cellular DNA, 65 of which investigate the effects of exposure to ionizing radiation and 26 of which study the consequences of exposure to ultraviolet radiation.

Thirty-three grants and two contracts fund studies in radiation carcinogenesis ranging from those which investigate basic research on mechanisms to those that address radiation risks and the compilation and assessment of information relevant to risk assessment.

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The extramural activities of the Branch are accomplished through contractual agreements with universities and other Federal agencies, and through traditional individual research grants (R01), conference grants (R13), First Independent Research Support and Transition (FIRST) Awards (R29), program project grants (PO1), Small Business Innovative Research (SBIR) grants (R43/44), Outstanding Investigator Grant (OIG) Awards (R35), Methods to Extend Research in Time (MERIT) Awards (R37), and Academic Research Enhancement Awards (AREA) (R15). At present the Branch administers 131 extramural research activities with an annual budget of 19.75 million dollars (Tables I and II). The program consists of two broad categories of research: mechanisms of radiation damage and repair, and radiation carcinogenesis. In addition, the NIH and the NCI have assigned to the Branch responsibility for the implementation of a section of a Public Law addressing radiation-related issues emanating from congressional policy concerns.

Section 7(a) of Public Law 97-414, the Orphan Drug Act, requires the Secretary to conduct scientific research and prepare analyses necessary to develop valid and credible (1) assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131, (2) methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear weapons fallout, and (3) assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests conducted during the years 1951-1963. Relevant expertise within and outside of the government has been mobilized to these issues: the risk of thyroid cancer per unit dose of Iodine-131 to the thyroid, the dose of Iodine-131 to the thyroid per unit of exposure to Iodine-131, and the development and verification of models to estimate the exposure of the American people to Iodine-131 resulting from radioactive fallout associated with atmospheric nuclear weapons tests at the Nevada Test Site. Extensive efforts have been expended in the identification, recovery, acquisition and analyses of a wide range of data relevant to the required exposure and dose reassessments; these efforts have been carried out with the assistance of staff expertise acquired for this purpose and via interagency agreements. Activities associated with items (2) and (3) above been completed during the present reporting period, and a final report has been reviewed prior to printing. Item (1) is closely related to the thyroid studies in the republics of the former Soviet Union indicated above and discussed below.

Reviews and analyses of fallout source terms and available monitoring data for each of the atmospheric tests have been completed. In addition, meteorological conditions at multiple altitudes at the time of each test, together with wind and precipitation patterns across the United States during the days the fallout cloud was over United States territory, have been reconstructed. These data form the bases upon which statistical interpolation and extrapolation of fallout levels (i.e., ground surface levels) of Iodine-131 have been made for each of the then-existent 3,071 counties within the continental United States for each of the tests.

Since the primary exposure of the public to Iodine-131 following the tests was via the consumption of milk produced by grazing cows, milk production and distribution patterns, by county, were reconstructed. This methodology resulted in estimates of Iodine-131 concentrations in milk in each county and included the consideration of such factors as the location and times of the year when dairy herds were on pasture in relation to the date of each test and the areas from which milk was mixed. These estimated Iodine-131 concentrations in milk, combined with demographic information and individual consumption rates, permit an estimate of Iodine-131 exposure for residents of each county as a function of age and sex. These exposure estimates have been completed.

Under the auspices of agreements between the United States and Belarus, Russia and Ukraine for studies related to Civilian Nuclear Reactor Safety, the NCI and the REB, together with other components of the NIH, at the request of and under an Interagency Agreement with the Department of Energy, have been working with the Ministries of Health of each of the three countries, and with appropriate institutes and centers within the Ministries, to develop and implement, as appropriate, joint long-term studies of thyroid disease, especially cancer, among children exposed to radioisotopes of iodine as a result of the Chernobyl nuclear power plant accident, and of leukemia among the clean-up workers. A case-control study of 107 children in Belarus with thyroid cancer is nearly complete, including the review of medical and pathology records, identification and selection of control subjects, and initial estimates of the radiation doses to the thyroid of all case and control subjects. Following two years of discussions with Belarussian and Ukrainian authorities, scientists and physicians, prospective cohort studies, including individual dose reconstruction, to identify and follow approximately 15,000 children in Belarus and 70,000 children in Ukraine for thyroid cancer was agreed upon; these research protocols have been approved by scientific peer-review committees, by Institutional Review Boards (IRB) in each country, and by the Office of Protection from Research Risks of the National Institutes of Health. Separate agreements to implement these studies were signed by the Department of Energy and the Ministers of Health of Belarus and of Ukraine, and joint implementation activities were begun. Efforts also are being made in Ukraine to initiate a case-control study of thyroid cancer among children. These activities are coordinated with the Departments of State and Energy and, as appropriate, other U.S. entities (e.g., U.S. embassies, the Nuclear Regulatory Commission, private organizations) and international organizations (e.g., Commission of the European Communities, World Health Organization).

The Branch also was responsible for the development of a Memorandum of Understanding (MOU) between the NCI and NASA that was approved by both agencies during the year. The principal objective of the MOU is "to establish collaborative science planning and joint funding of radiation research and technology of applicability to common programs." The initial cooperative effort to implement the MOU was a workshop on "Mechanisms of Transmissible Genomic Instability from the Exposure of Mammalian Cells to Ionizing Radiation," held on August 3-4, 1995, and sponsored by the Branch and the Office of Life and Microgravity Sciences and Applications, NASA.

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Research activities in these programs are concerned with a wide variety of radiation effects including mechanisms of damage and repair of DNA by ionizing and nonionizing radiation, and radiation carcinogenesis. The Branch administers 131 extramural research activities, including 122 traditional grants plus supplements to 9 of these grants. The majority of the 122 grants (92) support investigations relating to mechanisms of radiation damage and repair of cellular DNA, 72 of which investigate the effects of exposure to ionizing radiation and 20 of which study the consequences of exposure to ultraviolet radiation. Thirty grants fund studies in radiation carcinogenesis ranging from those which investigate basic research on mechanisms to those that address radiation risks and the compilation and assessment of information relevant to risk assessment.

ATTACHMENT

12

note Date: May 5, 1993

To: Sue Feldman

Subject: Program Advisory Committee Assessments

Attached are the "Assessment" sections of the OMB ATTACHMENT form for each of the five (5) NCI Program Advisory Committees cited in your memorandum of April 27th to the Director, NCI.

A copy of the pertinent statute is included in the one case where it is applicable. A WordPerfect disk copy of the text of the assessment sections is also provided.

Please let me know if additional information is required.

Barbara S. Bynum

Attachments

cc: Dr. Broder
Ms. Tisevich
Ms. Frank, CMO, NCI

Department of Health and Human Services
National Institutes of Health:
NCI THYROID/IODINE-131 ASSESSMENTS COMMITTEE

Recommendation (only one): _X_ Terminate ____ Merge ____ Continue

Committee statutory authority, cost, staffing and identification:

(a) Required by statute: Yes; specific authority: ________ No _X_

(b) Committee cost (FY 92 actual and FY 93 estimate): FY92 $12,599 FY93 $22,779

(c) Federal staff support years (FTE): FY92 Actual 0.2 FY93 Estimate 0.2

(d) Committee identification number: CA152

Committee Costs

	FY92 Actual	FY93 Estimate
PERSONNEL PAYMENTS		
Non-Fed. Members	0	750
Fed. Members	0	1,000
Fed. Staff	12,549	13,138
Non-Members Consult	0	0
TRAVEL AND PER DIEM		
Non-Fed Members	0	7,240
Fed. Members	0	576
Fed. Staff	0	0
Non-Member Consult.	0	0
Other	50	75
TOTALS	$12,599	$22,779

Department of Health and Human Services
National Institutes of Health:
NCI THYROID/IODINE-131 ASSESSMENTS COMMITTEE

Assessment

Though it was not required by statute, the NCI Thyroid/Iodine-131 Assessments Committee was established to assist the Director, NCI, and the Secretary of Health and Human Services in responding to Section 7(a) of Public Law 97-414 which directed the Secretary, DHHS, to: (1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131; (2) conduct scientific research and prepare analyses necesssary to develop valid and credible methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear bomb fallout; and (3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine-131 that the American people received form the Nevada atmospheric nuclear bomb tests.

Its membership consists of 12 persons who are authorities knowledgeable in such fields as radioactive fallout dosimetry, mechanisms of environmental transport of radionuclides, thyroid metabolism of Iodine, effects of radiation on the thyroid, epidemiology/biostatistics, and risk assessment.

Recommendation

The charter of this committee specifically states that the Committee should meet at least once each year, prepare and submit an annual report to the Secretary, DHHS, among others, and "terminate September 15, 1993, unless extension beyond that date is appropriately requested and approved."Because the charge to the Committee has been appropriately addressed in the conduct of its business, and because its significant accomplishments are now a matter of record, it is recommended that the Committee terminate on the prescribed date.

ATTACHMENT

13

INTERNATIONAL WORKSHOP ON

ENVIRONMENTAL DOSE RECONSTRUCTION

November 16, 1994
Atlanta, Georgia

THYROID DOSES FROM IODINE 131 TO THE U.S. POPULATION RESULTING FROM ATMOSPHERIC NUCLEAR WEAPONS TESTS CONDUCTED AT THE NEVADA TEST SITE

Dr. André Bouville
Senior Radiation Physicist
National Cancer Institute
Bethesda, Maryland

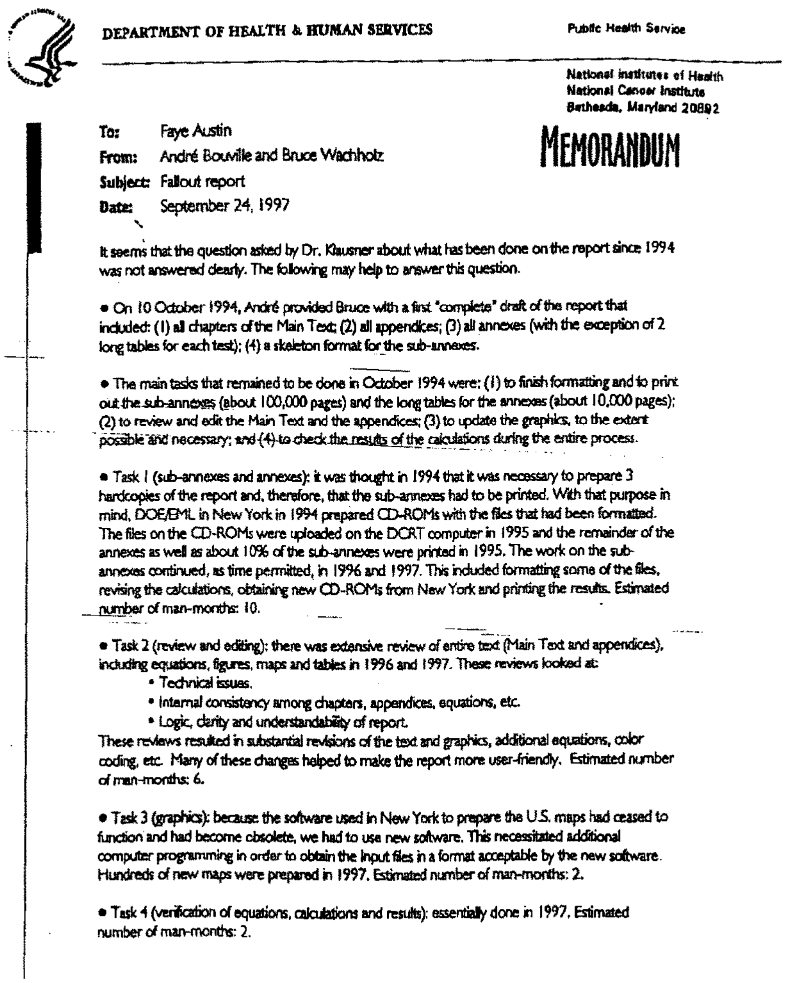
morning by Lynn Anspaugh. Howard Beck was really instrumental in estimating the depositions of iodine 131 throughout the country. We also had the help of NOAA, which is the United States Weather Bureau, if you would. And NOAA was responsible for all meteorological data and the precipitation data as well.

But also we had the help of non-government people. And first of all I list Lawrence Livermore National Laboratory, and Lynn Anspaugh in particular; Oak Ridge National Laboratory, that's where Owen Hoffman used to work, and Owen contributed to this study; RAC, which is Radiological Assessments Corporation, and John Till helped tremendously as well; SAIC, that's where Paul Voillequé used to work, and Paul is also a member of the thyroid committee. So he's one of the people who actually is responsible for the results of the study. And other people I would like to mention, Steve Simon, who also participated in this study. So you see quite a few people who are here participated in this study.

The study was conducted from 1985 to 1992. Practically all of the results have been available since 1992, since two years ago, but the report is still to come out, to be published. I say that we had to estimate the thyroid dose for each county of the United States, and here is your map representing all those counties. And Lynn Anspaugh told you this morning that the area we were working on was large, very large, but ours was even larger than that one.

ATTACHMENT

14



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

MEMORANDUM

To: Faye Austin
From: André Bouville and Bruce Wachholz
Subject: Fallout report
Date: September 24, 1997

It seems that the question asked by Dr. Klausner about what has been done on the report since 1994 was not answered clearly. The following may help to answer this question.

- On 10 October 1994, André provided Bruce with a first "complete" draft of the report that included: (1) all chapters of the Main Text; (2) all appendices; (3) all annexes (with the exception of 2 long tables for each test); (4) a skeleton format for the sub-annexes.

- The main tasks that remained to be done in October 1994 were: (1) to finish formatting and to print out the sub-annexes (about 100,000 pages) and the long tables for the annexes (about 10,000 pages); (2) to review and edit the Main Text and the appendices; (3) to update the graphics, to the extent possible and necessary; and (4) to check the results of the calculations during the entire process.

- Task 1 (sub-annexes and annexes): it was thought in 1994 that it was necessary to prepare 3 hardcopies of the report and, therefore, that the sub-annexes had to be printed. With that purpose in mind, DOE/EML in New York in 1994 prepared CD-ROMs with the files that had been formatted. The files on the CD-ROMs were uploaded on the DCRT computer in 1995 and the remainder of the annexes as well as about 10% of the sub-annexes were printed in 1995. The work on the sub-annexes continued, as time permitted, in 1996 and 1997. This included formatting some of the files, revising the calculations, obtaining new CD-ROMs from New York and printing the results. Estimated number of man-months: 10.

- Task 2 (review and editing): there was extensive review of entire text (Main Text and appendices), including equations, figures, maps and tables in 1996 and 1997. These reviews looked at:
    - Technical issues.
    - Internal consistency among chapters, appendices, equations, etc.
    - Logic, clarity and understandability of report.

These reviews resulted in substantial revisions of the text and graphics, additional equations, color coding, etc. Many of these changes helped to make the report more user-friendly. Estimated number of man-months: 6.

- Task 3 (graphics): because the software used in New York to prepare the U.S. maps had ceased to function and had become obsolete, we had to use new software. This necessitated additional computer programming in order to obtain the input files in a format acceptable by the new software. Hundreds of new maps were prepared in 1997. Estimated number of man-months: 2.

- Task 4 (verification of equations, calculations and results): essentially done in 1997. Estimated number of man-months: 2.

ATTACHMENT

15

DRAFT

RECENT HISTORY OF THE PREPARATION OF THE NTS FALLOUT REPORT

At the end of 1992, the calculations leading to the estimation of doses had been prepared and an extensive, but still incomplete, draft of the report was available. The work done from 1993 to date consisted essentially in:

6-12 years [illegible] Depends on [illegible] availability of [illegible]

- checking for possible errors in the equations and the calculations;
- completing the draft report and having it reviewed for subsequent revisions;
- revising the existing graphics and preparing new ones;
- transferring all computer files from New York to Washington;
- formatting the results in order to make them available in the form of Tables that could be easily read. Printing at least one copy of the Tables (representing more than 100,000 pages of text).

During this time, the involved staff essentially consisted of two persons, including the Branch Chief, who also had other major assignments. (see "The Chernobyl Project" under "Collateral Activities.")

Health Physics Society 1993-[illegible] [illegible]

1993

- Preliminary analysis of the complete data set was completed early in 1993.
- At this time, a substantial part of the database would have been unintelligible to anyone other than the programmer.
- A test was done to print at DCRT a number of computer files, which had been downloaded in New York on 9-track magnetic tapes. This test was not satisfactory; DCRT recommended the use of CD-ROMs. These files (about 10,000 pages) were printed on the DCRT computer. (3-4 weeks)
- The personal computer on which the mapping software was installed in Washington breaks down, deleting that software in the process. The original

mapping software (MAPMASTER) cannot be reinstalled (systematic error) or replaced as it had become obsolete.

- The advisory committee was arbitrarily disbanded by the NCI, resulting in at least three immediate effects:
    - The experts and collective resources available to the NCI from the committee until that time were no longer available for the completion of the report.
    - The demise of the committee, plus the fact that there had been no inquiry regarding this project from outside the Division for almost nine years, provided a very strong indication that this effort was not very urgent or important to the NCI or to others.
    - The absence of deadlines imposed by the committee or of the need to prepare material for committee meetings coincided with the increasing time and effort required to ensure the successful negotiations and development to establish viable thyroid cancer risk studies in Belarus and Ukraine.

1994

- January: presentation of the methodologies used in the study at the NATO meeting on "Radiation from Nuclear Test Explosions" in Vienna, Austria. (Dr. Bouville) Map
- Partial review of equations and calculations in the report checked by non-NCI experts.
- The first draft of the Entire ~~entire report (~~main text and appendices~~)~~ ? 10% of total data was completed in October. This did not include annexes and subannexes, which contained all data used to calculate estimates of individual doses.

DRAFT

- Most of the computer files stored in the VAX computer in New York are written on CD-ROMs and uploaded on the DCRT computer. (~ 1 month)

- November: presentation of paper at the CDC International workshop on Environmental Dose Reconstruction, Title: "Thyroid Doses from Iodine-131 to the U.S. population resulting from atmospheric nuclear weapons tests conducted at the Nevada Test Site." (Dr. Bouville) May

- Electronic communication is established between the PC in Washington and the VAX computer in New York. (~ 1 week)

- Several related activities extending from May until December were undertaken in response to inquiries from Senator Byron Dorgan (ND) and from the ND State Department of Health and Consolidated Laboratories, Preventive Health Section (Stephen L. McDonough, M.D., Chief):

    - (April) NCI was asked by Dr. McDonough to provide I-131 data for five weapons tests for all counties in North Dakota and in Utah.

    - (July) Both estimated average I-131 deposition values and estimated average thyroid doses were provided for each of the counties in North Dakota and in Utah for each of the five weapons tests requested, plus three other tests, plus the estimates for the entire weapons testing program..

    - (May) Senator Dorgan requested that NCI review a report prepared by Dr. McDonough (at the Senator's request), "Downwind in North Dakota: An Uncertain Legacy." The report suggests a link between fallout from the Nevada Test Site and thyroid cancer (50-100 cases caused by I-131) and childhood leukemia (3-4 cases caused by Sr-90).

DRAFT

- (June) NCI responds positively to Senator Dorgan's request.
- (September) Extensive comments are provided to Dr. McDonough on his report.
- (December) NCI staff, together with DOE staff, met with Senator Dorgan, his staff and Dr. McDonough. Subsequent to this meeting, Senator Dorgan and Dr. McDonough decided to no longer pursue the matter. Dr. McDonough eventually published his report.
- (NOTE) Dr. McDonough acknowledges NCI data and assistance in his report, including estimated average thyroid doses for the state of ND.

1995

- Little was done on the report due to the demands needed to establish the basis for assessing the "risk" component of P.L. 97-414 via the large-scale studies of thyroid cancer among children in Belarus and Ukraine following the Chernobyl accident.
- April: presentation of an invited paper at the annual meeting of the NCRP, titled "Reconstructing Doses to Downwinders from Fallout." (Dr. Bouville)
~~May Version (map)~~
- Part of the Annexes and Sub-annexes (about 20,000 pages) are printed from the DCRT computer. (~ 1 month)

[illegible] detailed w [illegible]

1996

- Preparation of computer programs needed to reformat some of the subannexes. (~ 2 weeks)

DRAFT

- It was realized that the Radiation Effects Branch could not continue to focus so much time and effort on the Chernobyl studies at the expense of the completion of the I-131 fallout report.

- In June, an NCI senior staff member was transferred to the Branch to relieve some of the Chernobyl workload from the Branch Chief (especially now that the studies in both countries were becoming operational) so that he could resume efforts to complete and publish the I-131 fallout report.

- An internal penultimate review of the complete draft I-131 report was begun and a decision was made that the report must be released by October 1, 1997. (This decision was transmitted to CDC by letter dated March 10, 1997.)

- While previous reviewers had looked at the technical content of all or portions of the report, this penultimate review focussed on logic, internal consistency, uniformity, completeness, clarity and understandability of text and graphics, etc.

1997

- The penultimate review of the text and graphics continued, and revisions made and re-reviewed.

- Final checking of the methodology, data, and results by NCI staff and a non-NCI expert. (~ 3 weeks)

- Transfer of the remaining computer files from New York to Washington on CD-ROMs. This work necessitated renaming thousands of files. (~ 1 week)

- Preparation of over 100 maps with new software, necessitating further processing of the input files, and, as needed, writing new computer programs. (~ 1 month)

DRAFT

- Printing the major part of the Sub-annexes (about 80,000 pages). (~1 month)

- Final review of text, graphics, maps, tables, etc.
- Preparation of the entire report in electronic form, necessitating scanning the text and many Figures, maps and graphics, and converting a number of text files, originally prepared in a now obsolete word processing language (MASS11), into WordPerfect. (~ 2 months)

C:\RENEE\FALLOUT.PRO

ATTACHMENT

16

II. Timetable/Tracking/Why Did It Take So Long

A. Why did the study take so long? When did you get the first results?

The study took 14 years to complete because it involved, first the development of a methodology; then the identification, collection, and synthesis, of an enormous amount of data from many sources; the analysis of that data; and finally the review and refinement of the analysis by NCI staff and outside experts.

Preliminary calculations of per capita average exposures were confirmed in 1993. They were presented at professional meetings in 1994 and 1995.

Details:

1983-1992

- established advisory committee and task groups
- received available information from relevant studies
- identified and collected data from other federal and non-federal sources: the Department of Energy, the National Oceanic and Atmospheric Administration, the Department of Agriculture, the Department of Commerce, agencies in many states, the American Dairy Herd Improvement Association, the dairy industry and private individuals.
- identified which atmospheric and-underground nuclear tests released I-131 beyondthe boundaries of the Nevada Test Site.
- estimated I-131 fallout deposited on the ground on the basis of (1) a reanalysis of original gummed film (i.e., sticky paper) fallout monitoring stations at up to 95 locations across the U.S., (2) precipitation records and (3) mathematical modeling techniques to extrapolate estimates to each county of the U.S.
- estimate I-131 fallout deposited on the ground by means of meteorological dispersion models and precipitation data for those tests for which there were no monitoring data.
- estimated how much I-131 entered food chain (milk, leafy vegetables, etc.) based upon amount of I-131 deposited, precipitation data, pasture interception and retention of I-131, pasture grazing times and practices, and milk production and distribution data.
- prepared and regularly revised initial drafts of portions of the report as additional information became available.
- presented and published reports on methodologies
- estimated national per capita dose of 2 rads based on incomplete information,.
- estimated thyroid doses to limited selected examples of representative age groups in each county using assumptions regarding consumption of cows' milk, other foodstuffs and inhalation for all tests.
- sent report to outside reviewers; comments led to more revisions.

1992-1994

- completed acquisition of data in 1993.
- estimated thyroid doses to representative age groups in each county for each of 4 scenarios of milk consumption together with consumption of other foodstuffs and inhalation.
- confirmed previous preliminary calculation of national per capita dose.
- completed preparation of annexes (~10,000 pages).
- completed first complete draft of report, its appendices, and it's annexes.
- presented results (average per capita doses and final methodologies) in 1994 (at the annual meeting of the Health Physics Society and at a CDC workshop on dose reconstruction).

1994-1997

- formatted and printed sub-annexes (~90,000 pages).
- reviewed and edited the report and its appendices to make them more user-friendly (e.g., internal consistency among chapters and appendices (which had been prepared by different persons/groups), clarify equations and graphics, ensure logic, etc.)
- completed new programming for the hundreds of maps illustrating the results for the various deposition, food concentrations and thyroid doses due to I-131 by county, age, milk source, test/test series, etc.
- verified of all equations, calculations and results.
- presented and published average per capita results nationally (at the annual meeting of the National Council on Radiation Protection and Measurements) and internationally (at a meeting of the International Atomic Energy Agency) in 1995.

B. Why weren't the results released as soon as you had them? What have you been doing since 1993?

The results were considered preliminary; there was still a great deal of checking and review to be done before publication. Results by county and test were checked and formatted in order to prepare the annexes and subannexes of the report (about 113,000 pages). In addition, the narrative part of the report was revised several times in accordance with review comments. Articles relating to the study were prepared, presented, and published.

C. How could the study have been done faster? Are there other studies that have taken this long? Have you taken steps to ensure that this kind of delay does not occur again?

1. It could have been done faster by giving it a higher priority in the face of other demands on the researchers' time. However, NCI did not recognize the intensity of public interest in this particular study and did not ensure that it maintained its priority when competing demands needed

to be met.

2. It is not always possible to predict how long a study will take. While most grants may be funded for a 3-5 year period, quite often the studies themselves evolve into much longer studies of the original cohort, or branch off into other related areas using the original data.

3. NCI staff have already begun developing a tracking system of congressionally mandated activities that will be monitored and updated regularly, and will be available on the NCI's web site for staff and others to review.

D. When you began the study, what was the timetable? When did you expect to have the results? Who made that original timetable?

No timetable was ever established by Congress, DHHS, or NIH, though it has always been expected that this would be a lengthy study. Internal timetables were established by investigators, workgroups, and the advisory committee, but as the study unfolded, these proved to be unrealistic and optimistic.

ATTACHMENT

17

January 31, 1995

Betsy --

I very much regret that I have not had an opportunity to discuss these thoughts with Dr. Boice. I have called him three times and asked that he return the call, but he has not yet done so.

Since you already have received a copy of Dr. Boice's comments on your draft memorandum, there seemed to be little point in incorporating his comments into mine, and therefore I have not done so.

It is presumptuous and perhaps inappropriate of me to refer to the Radiation Epidemiology Branch without his awareness, especially in the context of an issue concerning which Dr. Boice has very strong opinions (with which I totally agree on a scientific basis), and I hope that he will not object to my musings since they are merely thoughts regarding possible considerations of the Senator's potential request. I don't appreciate the possibility of devoting and consuming Branch resources and personnel to a pointless effort of this nature (and insignificance) any more than Dr. Boice does; we all have more than enough to do of a much more productive nature, and I, too, hope that any further attention to this matter can be avoided.

There may be perspectives other than science involved here, however, and ultimately the NCI response may be based upon policy considerations and judgements as well as scientific ones. In this context, all options deserve attention, whether or not they are desirable.

Bruce

cc: Dr. Fraumeni
Dr. Boice
Dr. Bouville
Dr. Land

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date January 31, 1995

From Chief, Radiation Effects Branch BWW

Subject Some thoughts on your draft "Request for Followup Information on Radiation Fallout Data" in anticipation of a letter of request from Senator Dorgan that has not yet been received

To Betsy Duane, NCI

The "Background" is correct and DOE's response has not changed as of this date.

With respect to the expected request from the Senator, based upon his letter to DOE, it seems to me that there are at least three questions that should be considered:

1. Can it be done?
2. Should it be done?
3. Should NCI do it?

Can it be done?

The Senator makes two requests:

1. Examine childhood leukemia mortality in northern plains states and states exposed to heavier NTS fallout.

2. Estimate possible leukemia and thyroid cancer from the fallout.

These requests have been discussed with knowledgeable scientists both on NCI staff and outside NCI. The unanimous opinion is that these requests can be answered.

Mortality records presumably exist and can be examined to determine whether there was a difference during specified time periods (e.g., the 1960s compared to other decades). Obviously this comparison will combine all of the factors that may influence mortality data (e.g., fallout, diagnostic sophistication, earlier detection and treatment, etc.); nevertheless, presumably mortality data exist and can be compared.

The estimation of leukemia and thyroid cancer presumably also can be estimated even though the results may have little scientific meaning because of uncertainties, assumptions, extrapolations, etc. Dr. Bouville can retrieve from his data file estimated thyroid dose estimates categorized by state, county, diet, age and sex for each weapons test so long as the fallout cloud was over the U.S. [The development of these thyroid dose estimates were mandated by Public Law 97-414, Section 7(a).] Similarly, the Department of Energy will work with NCI to provide whole-body dose estimates by state and time. Of course, there again are considerable uncertainties in these dose estimates (which were calculated more than 30 years after the tests occurred), but they can be made.

I understand also that there exist risk coefficients that can be applied to these dose values both for thyroid cancer and for leukemia. While there is no accepted risk coefficient for thyroid cancer resulting from exposure to I-131, the National Council on Radiation Protection and Measurements (NCRP) has published guidance on this matter. The NCRP relates this coefficient to the risk of thyroid cancer following exposure to external radiation, the most recent analysis of which is in press and authored by eight scientists, five of whom are on NCI staff. Again, there are large uncertainties in estimating thyroid cancer cases from fallout, but presumably it could be done.

The data base for leukemia risk coefficients for whole-body exposure to radiation is stronger than that of thyroid cancer from I-131, and there exists a considerable literature regarding this relationship.

Finally, the North Dakota Department of Health already has made estimates of fallout-related leukemia and thyroid cancer based upon dose and risk information provided by Drs. Bouville and Land. It might raise questions of NCI responsiveness to now say that the same could not be done for other states.

Consequently, based upon the opinions of persons who are familiar with and work with these data, the answer to the first question is, "Yes, it can be done," recognizing that there are many uncertainties associated with any answer, and that any such estimates are likely to be lost in the noise and range of normal values such that the calculated increase is likely to have little or no meaning.

Should it be done?

There is unanimity of opinion that this would be a senseless exercise and a waste, if not misuse, of increasingly scarce financial and human resources.

The Utah studies are the primary example of what can or cannot be accomplished with even the most highly exposed populations. However, an increase in childhood leukemia was discernible and thyroid cancers showed a non-significant association with dose which was significant only if all thyroid neoplasms were combined. Of course the thyroid doses in Utah were higher than would be expected in the northern plains.

Equally important, however, is the policy dimension of our response. With NCI involvement in or support of radiation-induced leukemia and thyroid studies from Japan to Utah to the Baltics, Russia, Belarus and Ukraine, consideration must be given to the perception of a senator if NCI balks at responding positively, at least to some extent. Should he inquire of scientists at other research institutions as to the feasibility of his requests, he may well receive a positive reply; this would not reflect well on NCI.

Rather than to respond that this cannot be done, it might be more candid to address the futility of doing so. This was already discussed to no avail in our meeting with the senator and Dr. McDonough on December 16, and so is unlikely to be persuasive against his political instincts that "something" should be done. I doubt very much that the senator is in any way interested in enlarging a scientific data base with respect to dose-effect relationships, which probably would be the basis for any NCI interest, but he no doubt is very interested in exploring whether his constituents (and those in surrounding states) were affected by the fallout--even if only in theoretical terms. However, if an increase in either leukemia or thyroid cancer is discernible, this could lead to an enlarged study, perhaps even with similarities to the Utah study.

In summary, there are two answers to the question:

1. In terms of acquiring useful information, this "study" should not be done.

2. In terms of political, humanitarian and U.S.G. responsibility considerations, the response is an NCI policy call--whether it wishes to be helpful and responsive to the senator or to get out of this and hope that the senator won't pursue it either directly or in cooperation with senators/congressmen from other states (perhaps including Senator Hatch).

Should NCI do it?

If NCI chooses to be non-responsive to the senator, this question disappears (unless the issue is pursued by the senator at NCI, elsewhere in the U.S.G. or at other institutions).

If NCI agrees to either or both of the senator's requests, it/they can be carried out in either of two ways:

1. Intramurally--a combination of the Radiation Effects Branch and the Department of Energy (fallout values and dose estimates) and the Radiation Epidemiology Branch (risk coefficients and estimates of leukemia and thyroid cancer).

2. Extramurally--similar to the Utah situation--issue an RFP (or possibly a UO-1), select a contractor and monitor the work carried out.

As useless as this exercise would be, the first option would be cheaper in time and in dollars but more consuming of staff time from two branches with little in the way of scientific results to show for it. Also, it would prevent staff from carrying out more important and useful studies, and would take the equivalent of 4-6 months full time just to provide all of the dose estimates. (Of course, with other responsibilities, this time would be even greater.)

The second option probably would be much more expensive and also would require considerable staff time, although more in administrative and oversight activities than in science, and so would most likely consume more staff time of the Radiation Effects Branch and less staff time of the Radiation Epidemiology Branch. The process of issuing and awarding an RFP (or UO-1) would be at least 12 months, assuming that the BSC (and NCAB (?), to whom the Utah contract was taken) approves. Monitoring and perhaps an advisory group also would be required. Again, the doses would need to be provided by the Radiation Effects Branch and DOE, with administrative duties handled by the Radiation Effects Branch and with staff involvement from the Radiation Epidemiology Branch, either in an advisory capacity (as was the case during the Utah study [carried out via an RFP]) or in participatory role (UO-1)..

Since the bulk of time and effort would be in response to the senator's request for the leukemia and thyroid cancer estimates from fallout, perhaps a more limited but still satisfactory response (to the senator) would be to look at the mortality records for childhood leukemia in the northern plains states and defer any further commitment to see if such an analysis reveals anything of substance. (The same could not be done for thyroid cancer since mortality is rare and incidence is not available.) This would take less time and money, would give evidence of NCI's responsiveness, and would at least defer if not avoid the major commitment of staff and resources toward the leukemia and thyroid cancer estimates. This also has the advantage of looking at real cases rather than estimating hypothetical ones. If nothing is seen by such an examination, the argument could be made that it is not a prudent use of scarce resources to pursue what might have been by initiating a mathematical analysis of thyroid and whole-body doses, and estimated health consequences. The risk, of course, is that something of substance might be observed that would make it awkward not to proceed with the estimates of leukemia and thyroid cancer. This, too, could be done either intramurally with NCI staff (perhaps even via one or more of the several EBP support contractors) or through extramural funding mechanisms (RFP).

Federal coordinating committees

Your comment that "there are no longer any Federal-level coordinating committees" is not quite correct. You had inquired about NCI advisory committees. I had responded that for a number of years there existed a formal federal advisory committee on the thyroid and radiation exposure. In implementing the policy of downsizing government, this committee was abolished and no longer exists. However, the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) within the White House Office of Science and Technology Policy continues to function. (CIRRPC consists of a Policy Panel and a Science Panel comprised of representatives from 18 and 14 agencies, respectively. Dr. Beebe and I represent HHS on the Science Panel.) In the past, the Department of Veterans Affairs has turned to CIRRPC for guidance in responding to a Congressional request for an epidemiology study among radiation-exposed veterans. CIRRPC did not endorse the study and the Congressional request was withdrawn. The present issue is not a request for an epidemiology study and so is less demanding, but NCI may wish to consider submitting any such request to CIRRPC for an opinion. (Personally I doubt that this would be useful. It could be perceived as stalling and since we have or can provide the dose estimates, it probably would only (1) delay our response, and (2) reinforce the opinion that scientifically this will be a useless effort--which we already know. It probably would still return to NCI for a policy decision.)

Summary

1. The requests are scientifically useless but are easily understandable, perhaps even reasonable, from the public's and a senator's perspective.

2. For NCI to say that a response is not possible may be disadvantageous to the credibility of the Institute.

3. Since NCI already has provided the doses and risk coefficients to North Dakota for estimating leukemia and thyroid cancer, and in general agreed with the results, it would be awkward for NCI to say that the same cannot be done for other states.

4. Consider responding positively to the senator's first request--an examination of childhood leukemia mortality in the northern plains states. This could be done through either the intramural or extramural programs.

5. Suggest deferment and reconsideration of providing estimates of leukemia and thyroid cancer from fallout until after (3) above is completed.

6 Perhaps consider referring the request (if received) to CIRRPC for "guidance."

7. At a time when the Administration and Congress are reviewing and judging agencies and their component parts by their responsiveness to their "customers" (presumably the public), this request deserves careful consideration, whatever NCI's final response might be.

8. All options should be evaluated.

DATE: 2/10/95

FROM: Program Analyst, OLCA
Through: Director, OLCA

SUBJECT: Potential Request for Followup Information on Radiation Fallout Data

TO: Acting Director, DCE

BACKGROUND

On December 23, 1994, Senator Byron Dorgan (D-SD) asked the Department of Energy (DOE) to work with the NCI "to examine childhood leukemia mortality in northern plains states and states exposed to heavier NTS fallout and estimate possible leukemia and thyroid cancer from the fallout" (Attachment I). This would serve as followup action to the December 16 briefing NCI and DOE provided Senator Dorgan on this issue. NCI has not received a letter requesting this assistance, and I have learned that the Senator's new aide is unaware of this request to DOE.

DOE drafted a response for Secretary O'Leary's signature (Attachment II), which appears to commit NCI to this project. Dr. Bruce Wachholz, Chief, Radiation Effects Branch, has contacted DOE staff both verbally and in writing to express our deep concern that DOE refrain from committing this agency to any activity (Attachment III). DOE staff have been unable to assure Dr. Wachholz that the Secretary will not sign the letter.

It should be noted here that neither the Senator nor Dr. McDonough acknowledged our suggested changes to the "McDonough Report," which would clarify scientific data and limits to their interpretation. The report was published and discussed at a press conference in early January 1995. While the numerical computations concerning cases of thyroid cancer and leukemia were not unreasonable, misleading statements and conclusions about the scope of the problem, and about the role of fallout in multiple myeloma and breast cancer, are not supported by available scientific data and were expressly not supported by NCI during the December 16 meeting.

NCI STAFF PERSPECTIVES

Both Dr. Wachholz and Dr. John Boice, Chief, Radiation Epidemiology Branch, have serious concerns about this potential request. Although Senator Dorgan and Dr. McDonough may believe the data are immediately and easily available to answer his request, a two-day response is not possible. Presuming that all the data necessary for calculating risks from I-131 fallout were available, the large uncertainties from such estimations and the small populations available for study would preclude results of any scientific merit or information useful to the general population.

Furthermore, the scope of the response certainly places it in the "research project" category, requiring major commitments of staff time and resources. Should staff be designated fulltime to this project, it is estimated it could take up to 6-9 months without interruption from other duties. If staff were to undertake this in conjunction with ongoing job requirements, this study would take perhaps two years. NCI would need to consider carefully the scientific merit of such a project, especially given the serious workforce reductions underway and planned, and our increasingly limited flexibility with research funds.

In the past, NCI committed itself to a long-term study of fallout effects in Utah, which received the highest levels of fallout from nuclear testing of any State in the U.S. After years of intense investigation, the results were inconclusive. Overall, there was a statistically significant relationship between exposure to fallout and the occurrence of thyroid neoplasms; however, there was no statistically significant association with thyroid cancer. For leukemia, the overall finding was a weak dose-related association for all forms of leukemia and all ages. While this relationship was not statistically significant, the stongest statistical effect was seen with childhood leukemias occurring in Southwestern Utah. For both diseases, it is difficult to rule out the possibility that the observed associations might be due to chance. In fact, the thyroid study had the most potential to detect a relationship with fallout levels because it was a further follow-up of a previously identified cohort of affected children and involved clinical examinations of the thyroid.

Thus, NCI does have considerable interest and expertise in this area. Although NCI staff felt that these points were brought out quite clearly at the December 16 briefing, perhaps we were not as clear as we should have been that similar studies in States more distant from the Nevada test site will not yield results of any scientific merit.

ACTION

Specific action is not required until we receive a direct request from Senator Dorgan. However, NCI staff have expressed strong concerns as to what an appropriate response might be, given the assistance we have provided in the past, uncertainty about the DOE response, and our competing scientific needs. Staff must determine whether this potential project should be undertaken by the NCI. If not, we should be prepared to defend our decision.

OPTIONS

Should NCI be asked by Senator Dorgan to undertake a study, NCI could:

(1) Decline to undertake the project based on the absence of scientific merit

(2) Consider outside involvement
  - through a research proposal
  - through an IPA with a scientist who would conduct the research here
  - through an Interagency Agreement to detail someone here to do the work

(3) Consider seeking comment or pursuit of this project by other Federal groups
  - Ms. Lily Engstrom, OER, pointed out at our staff briefing in December that the human radiation task force is now interested in "downwinder" issues
  - The Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) within the OSTP has been asked in the past to respond to a Congressional request for an epidemologic study among radiation-exposed veterans. CIRRPC did not endorse the study and the request was withdrawn.

(4) Agree to undertake the project

Note that under all but option (1), significant NCI staff time still would be required to prepare and provide all fallout exposure and dose estimates.

Please let me know how you wish to proceed.

Betsy

Betsy Duane

Attachments

cc: Dr. Sondik
Dr. Sieber
Dr. Wachholz
Dr. Fraumeni
Dr. Boice
Dr. Land
Dr. Bouville
Ms. Kiser, OLPA
Ms. Engstrom, OER

BYRON L. DORGAN
NORTH DAKOTA
[illegible]

United States Senate
WASHINGTON, DC 20510–3405

STATE OFFICES:
[illegible]

December 23, 1994

The Honorable Hazel O'Leary
Secretary of Energy
Department of Energy
1000 Independence Ave., S.W.
Washington, D.C. 20585

Dear Secretary O'Leary:

On January 6, 1994, I wrote to the Department of Energy and the North Dakota State Health Department and Consolidated Laboratories (NDSDHCL) requesting a study be conducted on the possible health effects from the atmospheric testing at the Nevada Test Site (NTS). The Department of Energy and National Cancer Institute have been most helpful in assisting researchers in furthering the body of knowledge on this subject.

The NDSDHCL has completed a study of health effects in North Dakota from Nevada Test Site fallout. Although being careful not to come to premature conclusions, the NDSDHCL has noted that childhood leukemia mortality did increase in North Dakota during the 1960s. In addition, the NDSDHCL has calculated that between 3-4 cases of leukemia and 50 to 100 cases of thyroid cancer could have occurred as a result of NTS fallout. It is true that there is a large amount of uncertainty involved in estimating fallout related health effects nearly 40 years since the detonations occurred. However, the estimated number of cancers are greater than the NDSDHCL and I anticipated before the study began.

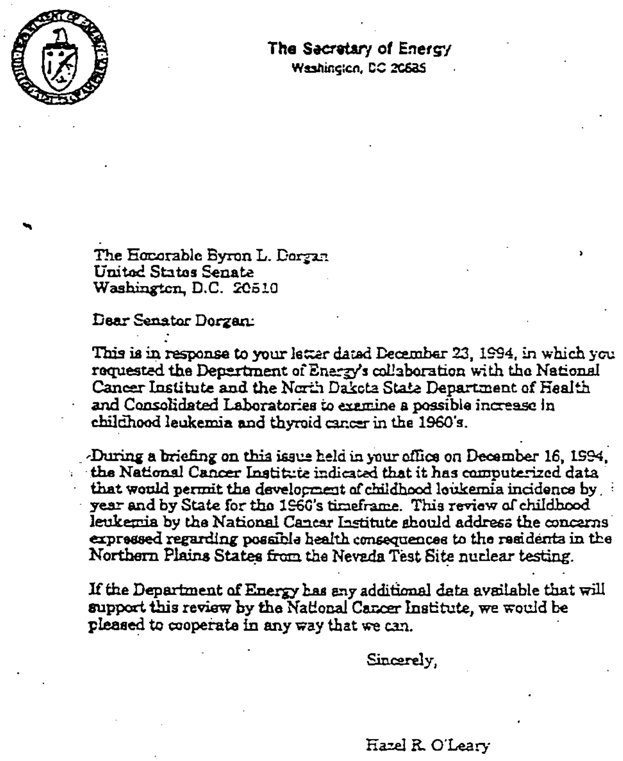
There is an opportunity here, I believe, to take a regional perspective in this issue. The National Cancer Institute is currently wrapping up a long effort to estimate doses from NTS fallout for every county in the United States. The National Cancer Institute also has the ability to calculate 1960's childhood mortality rates in northern plains states show an increase in childhood leukemia in the 1960's, then the possibility of NTS fallout as a cause deserves greater attention.

I am therefore requesting that the NCI, in collaboration with the DOE and the NDSDHCL, examine childhood leukemia mortality in northern plains states and states exposed to heavier NTS fallout and estimate possible leukemia and thyroid cancers from the fallout. I wish to thank you for your cooperation and assistance with this issue.

Sincerely,

Byron

Byron L. Dorgan
U.S. Senate



The Secretary of Energy
Washington, DC 20585

The Honorable Byron L. Dorgan
United States Senate
Washington, D.C. 20510

Dear Senator Dorgan:

This is in response to your letter dated December 23, 1994, in which you requested the Department of Energy's collaboration with the National Cancer Institute and the North Dakota State Department of Health and Consolidated Laboratories to examine a possible increase in childhood leukemia and thyroid cancer in the 1960's.

During a briefing on this issue held in your office on December 16, 1994, the National Cancer Institute indicated that it has computerized data that would permit the development of childhood leukemia incidence by year and by State for the 1960's timeframe. This review of childhood leukemia by the National Cancer Institute should address the concerns expressed regarding possible health consequences to the residents in the Northern Plains States from the Nevada Test Site nuclear testing.

If the Department of Energy has any additional data available that will support this review by the National Cancer Institute, we would be pleased to cooperate in any way that we can.

Sincerely,

Hazel R. O'Leary

Department of Energy
Washington, DC 20585

[illegible]

MEMORANDUM FOR THE SECRETARY

FROM: Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

SUBJECT: ACTION: Letter from Senator Byron L. Dorgan, Regarding His Request for Collaboration with the National Cancer Institute and the North Dakota State Department of Health and Consolidated Laboratories to Examine a Possible Increase in Childhood Leukemia and Thyroid Cancer in the 1960's

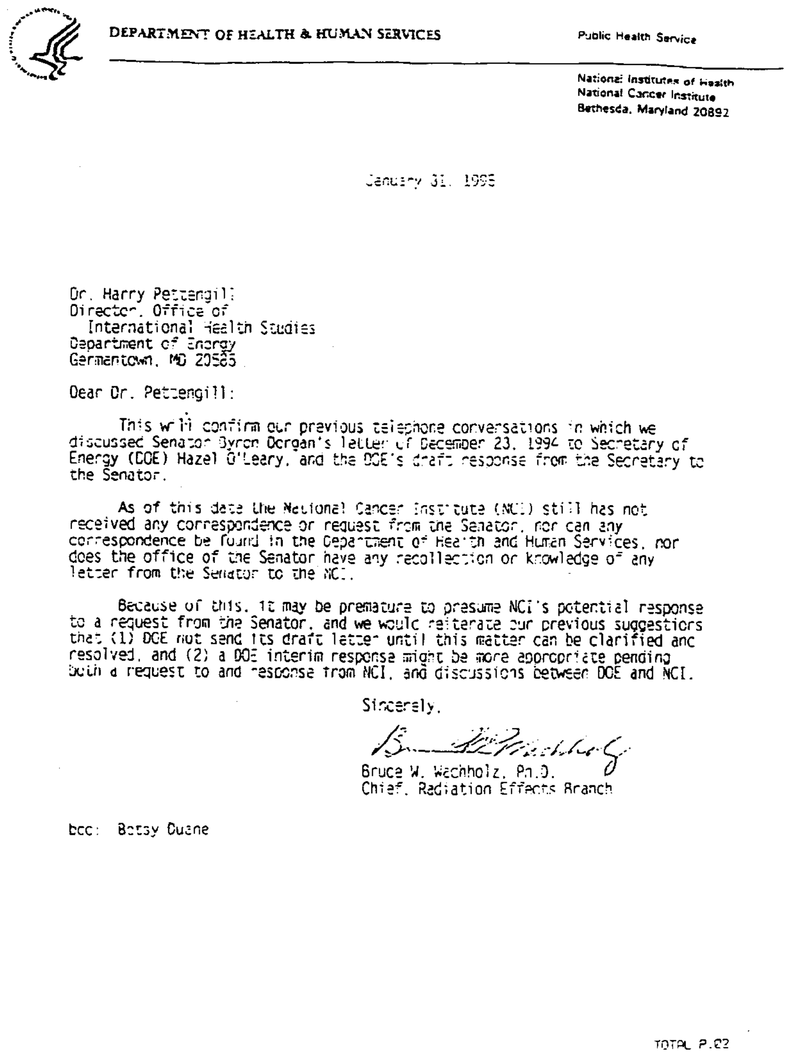
ISSUE: Obtain signature on the congressional.

- Senator Dorgan has forwarded a letter dated December 23, 1994, which is a followup to the briefing he received on December 16, 1994.
- The National Cancer Institute indicated that they had computerized data that would permit the development of childhood leukemia incidence by year and by State for the 1960's timeframe.
- Senator Dorgan is requesting that the National Cancer Institute examine childhood leukemia mortality and the incidence of thyroid cancers in the Northern Plains States exposed to heavier fallout from the Nevada operations. He is also requesting that the Department of Energy collaborate with the State of North Dakota and the National Cancer Institute on this review.

RECOMMENDATION: The Secretary sign the attached letter.

Attachment

Concurrence: Defense Programs/Reis / /95



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

January 31, 1995

Dr. Harry Pettengill
Director, Office of
International Health Studies
Department of Energy
Germantown, MD 20585

Dear Dr. Pettengill:

This will confirm our previous telephone conversations in which we discussed Senator Byron Dorgan's letter of December 23, 1994 to Secretary of Energy (DOE) Hazel O'Leary, and the DOE's draft response from the Secretary to the Senator.

As of this date the National Cancer Institute (NCI) still has not received any correspondence or request from the Senator, nor can any correspondence be found in the Department of Health and Human Services, nor does the office of the Senator have any recollection or knowledge of any letter from the Senator to the NCI.

Because of this, it may be premature to presume NCI's potential response to a request from the Senator, and we would reiterate our previous suggestions that (1) DOE not send its draft letter until this matter can be clarified and resolved, and (2) a DOE interim response might be more appropriate pending both a request to and response from NCI, and discussions between DOE and NCI.

Sincerely,

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

bcc: Betsy Duane

TOTAL P.02

MEMORANDUM

To: Bruce Wachholz

From: André Bouville

Date: March 22, 1995

Subject: Byron Dorgan's request.

I do not like the tone of the memo and its implication that the NCI staff is too busy to respond to Senator Dorgan's request.

I believe that what Senator Dorgan is after is objective information on the risks of childhood leukemia and thyroid cancer caused by NTS fallout. He is likely to be satisfied with a crude estimation of representative bone-marrow and thyroid doses in North Dakota and neighboring states followed by an estimate of the health effects obtained using risk coefficients extracted from the literature. The fact that epidemiological studies would be useless is irrelevant as I do not think that anybody is going to propose to conduct one.

In my opinion, most of the effort will consist in the estimation of bone-marrow and thyroid doses:

- Estimates of thyroid doses are available at NCI. They need to be confirmed, with a special look at the fallout data that are available in the North Dakota area. In order to do this, DOE needs to be involved.

- Detailed estimates of bone-marrow doses have never been prepared. DOE carried out back-of-the-envelope calculations to obtain average bone-marrow doses for North Dakota and to show that most of the dose was due to external irradiation from short-lived fission products and that the consumption of foodstuffs contaminated with Strontium-90 was only a small contributor to the bone-marrow dose. More refined estimates would have to be prepared. DOE has the primary data and should be responsible for the estimation of bone-marrow doses. NCI can only offer help to DOE in that area.

My position is that DOE should be responsible for the estimation of the risks of childhood leukemia and thyroid cancer caused by NTS fallout in North Dakota, and that NCI should not refuse to provide limited help. Of course, NDSDHCL should also be involved from the beginning.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

TELEFAX MESSAGE

TO:

Telefax:
Names & Address:
Betsy Duane

FROM:

Telephone: 301-496-9326
Telefax: 301-496-1224

Name & Address: Renee Castro for
Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Suite 530
Bethesda, MD 20892

DATE: March 14, 1995

NUMBER OF PAGES INCLUDING COVER PAGE: 4

NOTE:

I spoke to Dr. Wachholz last night and he told me that he faxed this to you on March 9. He has written on his copy and hoped that you would have a "clean" copy. If this is not what you need please let me know.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

TELEFAX MESSAGE

TO:
Telefax: 402-1225
Name & Address:
Betsy

FROM:
Telefax: 301-496-1224
Name:
Bruce
Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Room 530

DATE: 3-9-95

NUMBER OF PAGES INCLUDING COVER: 4

NOTE: Please review this ASAP and call me in the next 1/2 hour. I just rec'd it.

U.S. DEPARTMENT OF ENERGY
OFFICE OF HEALTH STUDIES
WASHINGTON, D.C. 20585

Date: March 9, 1995

To: Dr. Bruce Wachholtz, National Cancer Institute
301-496-9326

From: R. Thomas Bell
Supervisor, Pacific Health Programs
EH-63, GTN/270 Corporate Center
Office: (301) 903-3889
FAX: (301) 903-1413

Destination FAX number: 301-496-1224

No. of pages including cover sheet: 3

Comments:

Bruce:

I have been able to put on hold the signing of a letter to Dorgan for a couple of hours to possibly make changes but I can't kill it. There has been a lot of political pressure from Dorgan's office to answer the mail and they are impatient. Our congressional affairs folks have been taking a lot of flack and the Secretary's Office wants a letter out today. We worked up a softer version (on top with your name and fax on it). The letter that was ready to go out before we stopped it is the second one attached. I already have pre clearance for the new letter if you all concur. I will need input by 11:00 or it will go forward hopefully in the new version.

Tom

Tom - have you heard

Bruce Wachholz

9 496 9326

Fx 496-1224

The Honorable Byron L. Dorgan
United States Senate
Washington, D.C. 20510

Dear Senator Dorgan:

This is in response ~~to~~ your letter dated December 23, 1994, in which you requested that the Department of Energy's and ~~collaboration with~~ the National Cancer Institute collaborate together with and the North Dakota State Department of Health and Consolidated Laboratories to examine a possible increase in childhood leukemia and thyroid cancer in the 1960s.

During a briefing on this issue held in your office on December 16, 1994, the National Cancer Institute indicated its willingness to collaborate in addressing concerns regarding possible health consequences to the residents in the Northern Plains States from the Nevada Test Site nuclear testing. However, it is my understanding that to date the National Cancer Institute has not yet received a formal request from your office pertaining to these issues.

¶ The Department of Energy would be pleased to provide whatever information we have available to support such a collaboration. If you have further questions, please contact me or have your staff contact Dr. Heather Stockwell, Acting Director, Office of Epidemiologic Studies, on 301-903-3721.

Sincerely,

Hazel R. O'Leary

The Honorable Byron L. Dorgan
United States Senate
Washington, D.C. 20510

Dear Senator Dorgan:

This is in response to your letter dated December 23, 1994, in which you requested the Department of Energy's collaboration with the National Cancer Institute and the North Dakota State Department of Health and Consolidated Laboratories to examine a possible increase in childhood leukemia and thyroid cancer in the 1960s.

During a briefing on this issue held in your office on December 16, 1994, the National Cancer Institute indicated that it has computerized data that would permit the development of childhood leukemia incidence by year and by State for the 1960s timeframe. This review of childhood leukemia by the National Cancer Institute should address the concerns expressed regarding possible health consequences to the residents in the Northern Plains States from the Nevada Test Site nuclear testing.

If you have further questions, please contact me or have your staff contact Dr. Heather Stockwell, Acting Director, Office of Epidemiologic Studies, on 301-903-3721.

Sincerely,

Hazel R. O'Leary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

TELEFAX MESSAGE

TO:

Telefax: 32-2-772-22-17
Names & Address: Dr. Bruce W. Wachholz
c/o Dr. Omar Yoder/Ms. Radtke
NCI Liaison Office
BRUSSELS, BELGIUM

FROM:

Telephone: 301-496-9326
Telefax: 301-496-1224
Name & Address: Renee Castro
Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Suite 530
Bethesda, MD 20892

DATE: March 20, 1995

NUMBER OF PAGES INCLUDING COVER PAGE: 6

NOTE:

TELEFAX MESSAGE

TO:

Telefax: 402-1225
Name: Ms Betsy Duane
NCI/DIR

FROM:

Telefax: 301-496-1224

Name:
Dr. Richard A. Pelroy
Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Room 530
9000 Rockville Pike
Bethesda, MD 20892

ph (301)-496-9326

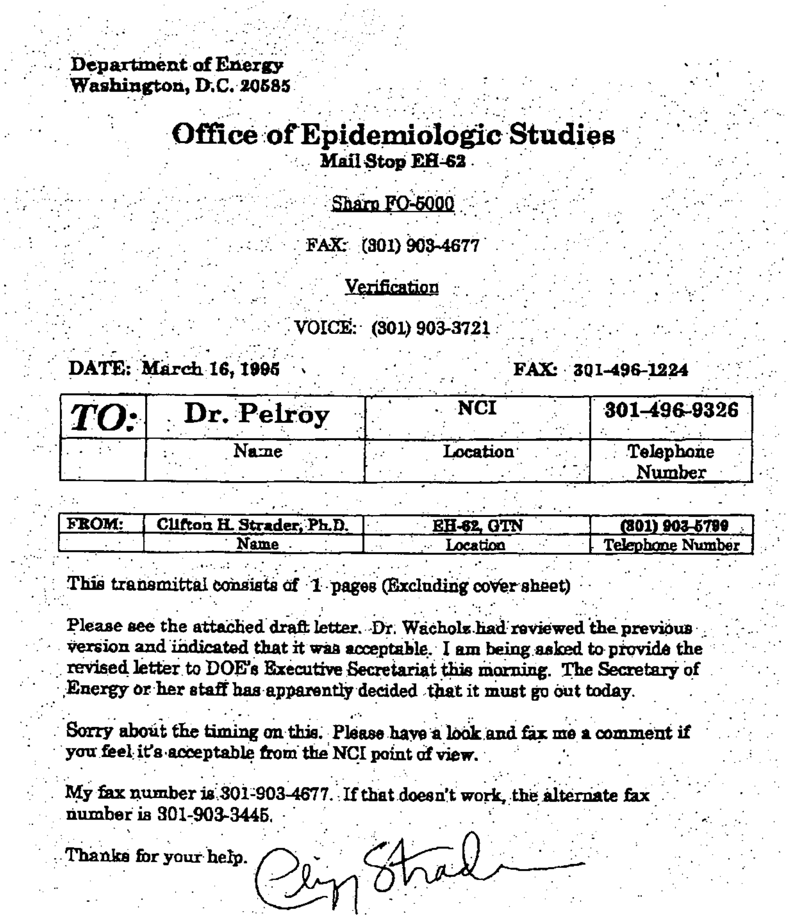
DATE:

March 17, 1995

PAGES TO FOLLOW: 4

NOTE:
Dear Betsy:
I have included all of the correspondence relating to the letter to Senator Dorgan from this morning. It includes: (a) the DOE fax cover and draft letter (incoming) and (b) the NCI fax cover and draft letter with suggested changes from the epidemiologists (outgoing). Dr. Strader called back, as I requested, and said that he would present our suggested changes (outgoing) and the original Dorgan draft letter (incoming) to the Executive Secretariat later on the morning of Mar 17. I hope this is helpful

Dick Pelroy



Department of Energy
Washington, D.C. 20585

Office of Epidemiologic Studies

Mail Stop EH-62

Sharp FO-5000

FAX: (301) 903-4677

Verification

VOICE: (301) 903-3721

DATE: March 16, 1995 **FAX: 301-496-1224**

TO:	**Dr. Pelroy**	NCI	**301-496-9326**
	Name	Location	Telephone Number

FROM:	Clifton H. Strader, Ph.D.	EH-62, GTN	(301) 903-5799
	Name	Location	Telephone Number

This transmittal consists of 1 pages (Excluding cover sheet)

Please see the attached draft letter. Dr. Wacholz had reviewed the previous version and indicated that it was acceptable. I am being asked to provide the revised letter to DOE's Executive Secretariat this morning. The Secretary of Energy or her staff has apparently decided that it must go out today.

Sorry about the timing on this. Please have a look and fax me a comment if you feel it's acceptable from the NCI point of view.

My fax number is 301-903-4677. If that doesn't work, the alternate fax number is 301-903-3445.

Thanks for your help. Cliff Strader

The Honorable Byron L. Dorgan
United States Senate
Washington, D.C. 20510

Dear Senator Dorgan:

At a December 16, 1994, briefing and in a December 23, 1994, letter you requested the Department of Energy's collaboration with the National Cancer Institute and the North Dakota State Department of Health and Consolidated Laboratories to examine a possible increase in childhood leukemia and thyroid cancer in the 1960s. We would be pleased to support such a collaboration.

As you are aware, the Department of Energy has provided extensive environmental fallout data to the State of North Dakota by the Coordination and Information Center at our Nevada Operations Office, Las Vegas, Nevada. These data were used in the preparation of the report Downwind in North Dakota: An Uncertain Legacy" released by the North Dakota State Department of Health and Consolidated Laboratories.

The National Cancer Institute has indicated its willingness to collaborate in addressing concerns regarding possible health consequences to the residents in the Northern Plains States from the Nevada Test Site nuclear testing. If the National Cancer Institute, in further coordination with your office, identifies other geographic areas for which environmental fallout data are needed, we will provide all available environmental fallout data for those states or geographic regions identified.

If you have further questions, please contact me or have your staff contact Dr. Heather Stockwell, Acting Director, Office of Epidemiologic Studies, on 301-903-3721.

Sincerely,

Hazel R. O'Leary

TELEFAX MESSAGE

TO:

Telefax:301-903-4677 or 301-903-3445
Name: Dr. Clifton Strader
Department of Energy
EH-62, GTN

FROM:

Telefax: 301-496-1224

Name:
Dr. Richard A. Pelroy
Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Room 530
9000 Rockville Pike
Bethesda, MD 20892

ph (301)-496-9326

DATE:

March 17, 1995

PAGES TO FOLLOW:

NOTE:
Dr. Strader
Attached are requested changes to your draft letter to Senator Dorgan. I'm sorry that I was not able to give them to you at 10:00 am this morning. However, it is my understanding that these suggested changes to the letter more accurately reflect the sense of the NCI representatives who were present at the briefing referred to in the letter, held during December, 1994. I would appreciate hearing back from you whether you were able to incorporate these suggested changes to the letter. Thank you.

Dick Pelroy

The Honorable Byron L. Dorgan
United States Senate
Washington, D.C. 20510

Dear Senator Dorgan:

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surveys of already been consulted

The National Cancer ~~Institute~~ has ~~indicated its willingness to collaborate in addressing~~ concerns regarding possible health ~~consequences to~~ the residents in the Northern Plains States related to fallout from the Nevada Test Site nuclear testing. If ~~the National Cancer Institute, in further coordination with your office, identifies~~ there are other geographic areas for which environmental fallout data are needed, we will provide all available environmental fallout data for those states or geographic regions identified.

If you have further questions, please contact me or have your staff contact Dr. Heather Stockwell, Acting Director, Office of Epidemiologic Studies, on 301-903-3721.

Sincerely,

Hazel R. O'Leary

NATIONAL CANCER INSTITUTE

NCI LIAISON OFFICE

Avenue E. Mounier 83
B-1200 Brussels
BELGIUM

Tel: +32/2/772.22.17
FAX: +32/2/770.47.54

FAX COVER SHEET

Date: 3-20-95

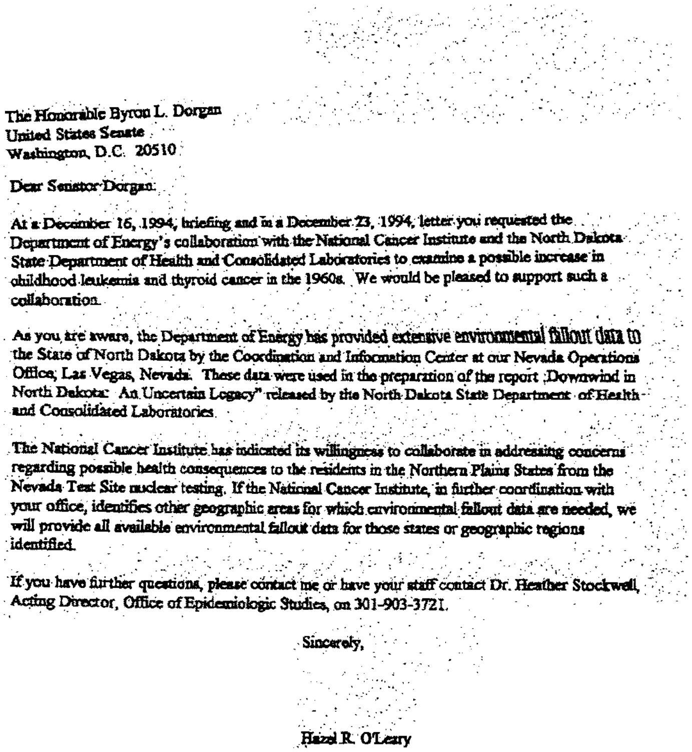
To: DR. TOM BELL

FAX N°: 301-903-1413 N° of pages: 2 (incl. cover)

From: BRUCE WACHHOLZ

Message:

FYI RE OUR TELECON



The Honorable Byron L. Dorgan
United States Senate
Washington, D.C. 20510

Dear Senator Dorgan:

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If you have further questions, please contact me or have your staff contact Dr. Heather Stockwell, Acting Director, Office of Epidemiologic Studies, on 301-903-3721.

Sincerely,

Hazel R. O'Leary

TELEFAX MESSAGE

TO:

Telefax:301-903-4677 or 301-903-3445
Name: Dr. Clifton Strader
Department of Energy
EH-62, GTN

FROM:

Telefax: 301-496-1224

Name:
Dr. Richard A. Pelroy
Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Room 530
9000 Rockville Pike
Bethesda, MD 20892

ph (301)-496-9326

DATE:

March 17, 1995

PAGES TO FOLLOW:

NOTE:
Dr. Strader
Attached are requested changes to your draft letter to Senator Dorgan. I'm sorry that I was not able to give them to you at 10:00 am this morning. However, it is my understanding that these suggested changes to the letter more accurately reflect the sense of the NCI representatives who were present at the briefing referred to in the letter, held during December, 1994. I would appreciate hearing back from you whether you were able to incorporate these suggested changes to the letter. Thank you.

Dick Pelroy

The Honorable Byron L. Dorgan
United States Senate
Washington, D.C. 20510

Dear Senator Dorgan:

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The National Cancer Institute has ~~indicated its willingness to collaborate in addressing concerns~~ already been consulted regarding possible health ~~consequences to~~ surveys of the residents in the Northern Plains States related to fallout from the Nevada Test Site nuclear testing. If ~~the National Cancer Institute, in further coordination with your office, identifies~~ there are other geographic areas for which environmental fallout data are needed, we will provide all available environmental fallout data for those states or geographic regions identified.

If you have further questions, please contact me or have your staff contact Dr. Heather Stockwell, Acting Director, Office of Epidemiologic Studies, on 301-903-3721.

Sincerely,

Hazel R. O'Leary

NCI Fax Transmittal

OFFICE OF LEGISLATION & CONGRESSIONAL ACTIVITIES
NATIONAL CANCER INSTITUTE

DATE: 4/14/95

TO: Bruce Wachholz

FAX NO. 6-1224

FROM: Betsy Duane

BLDG. 31 ROOM 11A23
Telephone: 301-496-5217
National Cancer Institute, Bethesda, Maryland 20892
FAX # 301-402-1225

Number of Pages (Including Cover Sheet) 7

ADDITIONAL COMMENTS:

FINAL DRAFT of the radiation fallout hearing summary, for your review before I distribute to the cc: list. I have done my best to incorporate a wide range of suggested changes, and have therefore scaled back the degree of detail. Please review the science to make certain my edits did not change the meanings, and make other changes you find necessary. Please let me know if you think this still needs significant work.

Date: April 14, 1995

From: Program Analyst, OLCA

Through: Director, OLCA ____

Subject: Brief Summary - December 16, 1994, Briefing for Senator Dorgan on Radiation Fallout

To: M/R

Participants:

North Dakota:

Senator Byron Dorgan

Mr. Steve Kroll, Legislative Assistant

Steven McDonough, M.D., State Department of Health and Consolidated Laboratories

Department of Energy:

Mr. Bruce Church, Assistant Manager for Environment, Safety, Security and Health, Nevada Operations Office

Mr. Dave Wheeler, Senior Health Physicist, Nevada Operations Office

National Cancer Institute:

Jerry M. Rice, Ph.D., Acting Director, Division of Cancer Etiology (DCE)

Bruce Wachholz, Ph.D., Chief, Radiation Effects Branch (REB), DCE

Andre Bouville, Ph.D., Senior Radiation Physicist, REB, DCE

Charles Land, Ph.D., Health Statistician, Radiation Epidemiology Branch, DCE

Other Attendees:

Mr. Alan Huffman, Staff to Senator Dorgan

Mr. Harold Beck, Deputy Director, Environmental Measurements Laboratory, DOE

Mr. R. Thomas Bell, Supervisor, Pacific Health Program, Office of International Health Studies, DOE

Mr. Don Youngberg, Environmental Scientist, Office of Defense Program, DOE

Mr. Al Knight, Office of Congressional Affairs, DOE

Ms. Dorothy Tisevich, Director, Office of Legislation and Congressional Activities (OLCA), NCI

Ms. Betsy Duane, Program Analyst, OLCA, NCI

Ms. Kristin Kiser, Program Analyst, Office of Legislative Policy and Analysis, National Institutes of Health

Senator Dorgan opened the briefing by declaring his own probable exposure during his childhood in North Dakota to fallout from atmospheric nuclear weapons tests conducted at the Nevada Test Site (NTS). His interest in this issue was sparked by the new openness of the Federal government regarding radiation experimentation, and he had asked the State Health Department to prepare a report on potential health effects from fallout. He expressed his desire for a full and open discussion focusing on whether all effects from fallout have been fully studied, and whether any further action should be taken.

Dr. McDonough summarized his efforts to create this report, and said he believes he has detected an increase during the 1960's of childhood leukemia in North Dakota. He remarked that he did not want the report to be inaccurate or increase the concern of citizens without cause, and would like to know more about neighboring states' fallout doses and cancer rates. He thanked NCI for having provided important feedback to his questions during this past year.

DOE staff described their dose-reconstruction efforts, which contributed to the dose assessment used in the NCI-sponsored University of Utah studies of leukemia and thyroid cancer. Dr. Wachholz added that Utah experienced the highest amount of fallout from the NTS, and that studies of radiation-induced thyroid disease and leukemia in that area were the most extensive in the United States. Yet the results of the thyroid studies were equivocal, and the results of the leukemia study did not yield any new information. While there was a weak association between dose and thyroid or leukemia risk, neither was statistically significant, and these results were consistent with accepted risk estimates. The Utah thyroid study was a followup based on a Public Health Service study from the mid-1960's, which also found no correlation between childhood thyroid cancer and fallout exposure.

During that same period, NCI was asked by Congress to study United States exposure to I-131 fallout from the NTS, the dose to the thyroid from such exposure, and the risk of thyroid cancer development. NCI has compiled the summary data, and preliminary estimates of thyroid doses have been prepared. Although these estimates have yet to be reviewed and published, data for North Dakota were provided to Dr. McDonough at his request. It should be noted, however, that ongoing NCI studies of children in Belarus and the Ukraine exposed to high levels of I-131 fallout from the Chernobyl reactor accident are expected to provide the most useful data for estimating a risk for thyroid cancer.

Dr. McDonough urged NCI to do a study across the United States of childhood leukemia mortality by county and year, to discern possible increases following fallout deposition. While age-specific county mortality statistics are available on which such a study could be based, participants generally agreed that given the low levels of expsoure that occurred, no scientific benefit could be expected from such a study.

Dr. Land explained that we already know a great deal about radiation-related cancer risk, based on studies of populations exposed to much higher doses. It is scientifically appropriate to base dose-response estimates on high dose exposure data and apply these estimates at lower doses. But if persons are studied after exposure only to low doses of radiation, it is difficult to differentiate true cancer risk from the "background noise" of random variations in cancer rates. While it may be reasonable, he supposed, that there was some increased risk in North Dakota, that risk essentially would be undetectable; for cumulative fallout doses would cumulative background doses, mainly from cosmic rays,

still be substantially less than ~~those~~ experienced by people residing in high-elevation areas such as Denver.

Dr. McDonough said that he did not think there was a substantial local cancer problem from global fallout, and did not think a study of thyroid cancer would be practical, given its low mortality rates and the lack of tumor registries in that region. But he referred to maps depicting bands of fallout across the Northern and Northeastern United States and wondered about the need for additional research on cancer epidemiology in those areas. He was cautioned again that there would be too few cases of any cancers, even by region, to measure or demonstrate causality.

Dr. Wachholz offered some suggested revisions to Dr. McDonough's report to clarify points of concern to NCI and DOE. He suggested that the perspective of the report was more alarming than the spectrum of research findings in this field warranted. Further description of underlying data and methodology, and their limitations and associated uncertainties, would be necessary to accurately convey the scientific results. Data should __not__ be extrapolated to cancers (such as multiple myeloma or breast) for which there is no scientific evidence of any relationship at the low doses under discussion. Dr. McDonough defended the tone of his report as a reflection of his own scientific conclusions that there was some cause for concern. Senator Dorgan added that it may be important to publicize a report merging pure science and speculation. Dr. Wachholz emphasized that the report should reflect an appreciation for wide uncertainty of the numbers.

Dr. Rice invited Dr. McDonough to visit NCI anytime to have the opportunity to refine his data and methodology conclusions, and to discuss these subject with NCI staff.

Betsy Duane

cc: Dr. Broder
Dr. Sondik
Dr. Rice
Dr. Sieber
Dr. Wachholz
Dr. Fraumeni
Dr. Boice
Dr. Bouville
Dr. Land
Ms. Engstrom, OER
Ms. Kiser, OLPA

Wachholz, Bruce

From: Duane, Betsy
To: Wachholz, Bruce
Subject: RE: Dorgan Hearing Summary
Date: Tuesday, May 09, 1995 2:38PM

I'm faxing it as I type - 2:45 pm Tuesday. Thanks!

REPLY FROM: Duane, Betsy
Microsoft Mail v3.0 IPM.Microsoft Mail.Note
From: Wachholz, Bruce
To: Duane, Betsy
Subject: RE: Dorgan Hearing Summary
Date: 1995-05-09 14:14
Priority: R
Message ID: D702F6AB
Conversation ID: D702F6AB

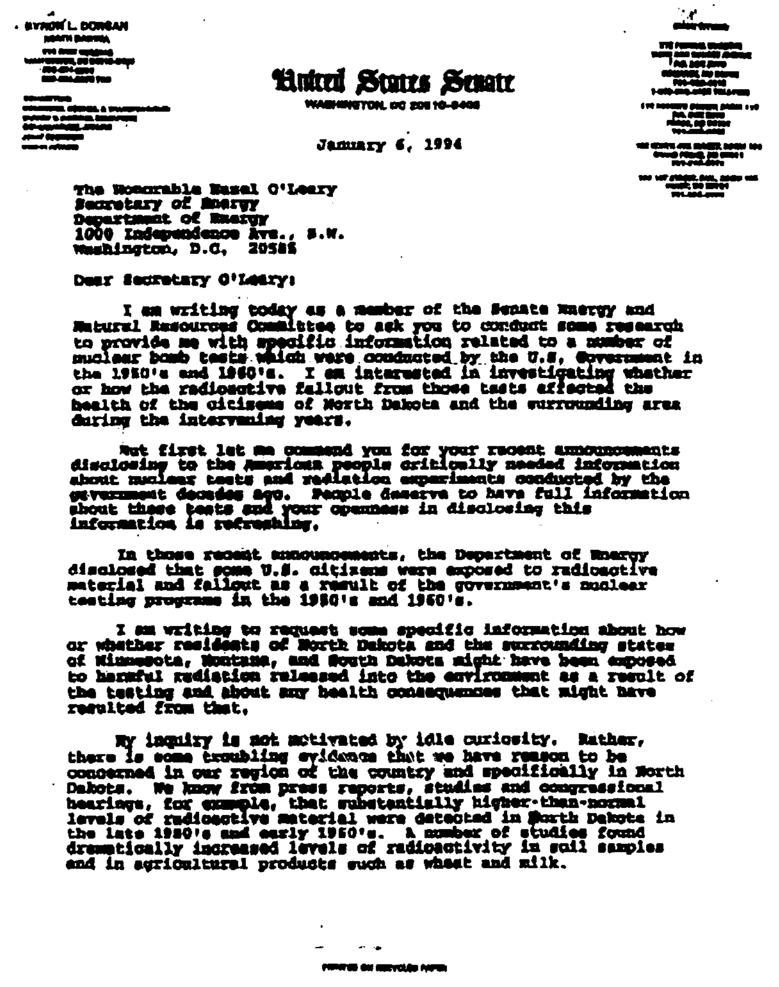
Betsy,

Would you please fax the final draft again. I haven't received anything from you for about a month or more. Thank you!

From: Duane, Betsy
To: Wachholz, Bruce
Cc: Duane, Betsy
Subject: Dorgan Hearing Summary
Date: Tuesday, April 25, 1995 1:30PM
Priority: High

Did you get my final draft for your review? I faxed it awhile ago - if you need it refaxed, I'll be happy to do it. Thanks!

ATTACHMENT A



BYRON L. DORGAN
NORTH DAKOTA

United States Senate

WASHINGTON, DC 20510-3405

January 6, 1994

The Honorable Hazel O'Leary
Secretary of Energy
Department of Energy
1000 Independence Ave., S.W.
Washington, D.C. 20585

Dear Secretary O'Leary:

I am writing today as a member of the Senate Energy and Natural Resources Committee to ask you to conduct some research to provide me with specific information related to a number of nuclear bomb tests which were conducted by the U.S. Government in the 1950's and 1960's. I am interested in investigating whether or how the radioactive fallout from those tests affected the health of the citizens of North Dakota and the surrounding area during the intervening years.

But first let me commend you for your recent announcements disclosing to the American people critically needed information about nuclear tests and radiation experiments conducted by the government decades ago. People deserve to have full information about these tests and your openness in disclosing this information is refreshing.

In those recent announcements, the Department of Energy disclosed that some U.S. citizens were exposed to radioactive material and fallout as a result of the government's nuclear testing programs in the 1950's and 1960's.

I am writing to request some specific information about how or whether residents of North Dakota and the surrounding states of Minnesota, Montana, and South Dakota might have been exposed to harmful radiation released into the environment as a result of the testing and about any health consequences that might have resulted from that.

My inquiry is not motivated by idle curiosity. Rather, there is some troubling evidence that we have reason to be concerned in our region of the country and specifically in North Dakota. We know from press reports, studies and congressional hearings, for example, that substantially higher-than-normal levels of radioactive material were detected in North Dakota in the late 1950's and early 1960's. A number of studies found dramatically increased levels of radioactivity in soil samples and in agricultural products such as wheat and milk.

PRINTED ON RECYCLED PAPER

Page Two
January 6, 1994

Many experts feel that these levels were related to the radioactive fallout clouds that moved directly across our state and region immediately following nuclear tests in Nevada. The testing that caused the raised radioactive levels was well documented in newspaper reports in the late 1950's. Of course no one knew what the effects of the radiation levels would be. The question is, do we now know?

In the book, Killing Our Own, the authors report that in the late 1950's "the northern Great Plains -- particularly the Red River Valley dividing North Dakota and Minnesota -- were fast becoming the most strontium-90-contaminated area in North America." In addition, a comprehensive series of articles on nuclear fallout indicated that strontium levels in milk in the Mandan, North Dakota area were among the highest in the country during the period of extensive nuclear testing. Other reports point to similarly disturbing problems in the Minot, North Dakota region.

I am especially interested in several nuclear bombs which were exploded in Nevada, and which some speculate created the clouds of radiation that traveled north and east across the northern Great Plains which then, because of rainfall pattern in the summer, caused substantial amounts of radiation to be dumped on North Dakota and surrounding areas.

The nuclear explosions I am interested in include, but are not limited, to the following:

1) Plumb Bob Wilson Bomb- exploded June 18, 1957,
2) Plumb Bob Diablo Bomb- exploded July 15, 1957,
3) Plumb Bob Kepler Bomb- exploded July 24, 1957,
4) Plumb Bob Franklin Bomb- exploded August 30, 1957, and
5) Plumb Bob Smokey Bomb- exploded August 31, 1957.

There are some who feel that specific nuclear tests which produced clouds of radioactive material, occurred at times that correlate with substantial rainfalls in North Dakota several days after the explosion in Nevada, and that the radioactive cloud dumped its material on our state as a result of rainfall when the clouds were moving across our region. For example, several days following the Plumb Bob Wilson bomb explosion in Nevada on June 18, 1957, the Fargo, North Dakota area had a substantial amount of rainfall (2.77 inches). This, some contend, is what contributed to the dumping of that radioactive cloud on that area of North Dakota.

I don't know whether these are only untested theories, or whether they are plausible explanations for the levels of radioactivity tested in North Dakota in the summer of 1957 and other periods following that. One thing we know for sure is that the U.S. Government was finding some of the highest levels of radioactivity they ever measured in the U.S. right smack in the middle of North Dakota and also in the Red River Valley between our state and Minnesota. And we also know that the federal government was concerned enough at the time to be conducting special and substantial radioactive testing in our state.

As a result of that information, and as a result of your willingness to disclose this important information to the American people, I now want the Department of Energy to do some research to provide me with information that I expect the government has collected over the years about this matter.

I want to understand now, with several decades of hindsight, what relationship the government determined existed between the nuclear tests and the radioactive levels in my state. I want some complete information about radioactive levels that have been measured over the years. I also want to know if the results of radioactive levels have been correlated with a monitoring of health consequences of radiation exposure in North Dakota, specifically with respect to various kinds of cancer such as bone cancer and leukemia, and more.

Here is some of the information I am requesting that the Department of Energy provide to me:

(1) Did DOE or its predecessors make an effort to study and evaluate the movement of radioactive materials through the country following the detonation of nuclear devices or other activities relating to the government's nuclear program (with special attention to the specific explosions cited above)? If the government made an effort to track or study the movement of clouds of radioactive fallout, what were the results of those studies? I would like all relevant information, especially details about abnormal levels of radioactive material measured in North Dakota during that period.

(2) Has the federal government in any of its studies or monitoring determined that North Dakota residents or other residents of our tri-state region have been exposed to harmful or dangerous levels of radiation released as a result of tests at

DOE's nuclear weapons facilities or test sites? I would like to be provided with all studies of radiation in North Dakota and the region during the testing period.

(3) Assuming abnormal levels of radioactivity were detected in North Dakota, did DOE or any other federal agency participate in a program to remedy or reduce this condition? For example, did DOE or other government agencies have milk removed from grocery store shelves in any North Dakota cities in the 1950's or 1960's? If so, what was the base of information which led the government to take such action? Can you cite all such actions taken, and can you provide me with any recommendations that may have been made which were not taken to respond to the results of radiation testing?

(4) Has DOE or any other federal agency conducted studies of the health hazards related to radiation exposure, such as abnormally high rates of leukemia, bone cancer, and infant mortality? Has your agency worked in concert with any state agencies to monitor the rates of various kinds of cancer that have occurred in various areas of our region and specifically in North Dakota? If so, have there been any conclusions developed that would correlate to the radioactive fallout from the early testing? I would like to be provided with any information that you have developed and any studies that have been conducted on this subject.

(5) If no such studies have been done, I want to request that you, in coordination with other federal agencies and with appropriate state and local health authorities, now begin a comprehensive analysis of any relationship that might exist between the nuclear tests, the high radiation levels in North Dakota, and the incidence of various types of cancer and other diseases in those affected areas.

I will greatly appreciate your assistance in determining any threat that may have resulted to the health and safety of North Dakotans as well as other Americans from these tests. I am going to ask the North Dakota State Health Department and other agencies to develop and analyze information about the incidence of certain kinds of cancer in parts of our state that might relate to the information I am seeking from you. It is our obligation to seek answers to these and other questions that have been raised over the years, and I ask for your help to do just that.

Thank you in advance for your prompt attention to this matter.

Sincerely,

Byron

Byron L. Dorgan
U.S. Senator

BLD:ach

[illegible] Hazel!

The Honorable Byron L. Dorgan
United States Senate
Washington, DC 20510-3405

Dear Senator Dorgan:

This is in response to your letter dated January 6, 1994, in which you indicated an interest in specific information related to a number of tests of nuclear explosive devices conducted in the late 1950's and early 1960's that resulted in radioactive fallout in the state of North Dakota.

I am aware of your concerns as a result of your meeting with members of the Office of Environment, Safety and Health staff that met with you on January 12, 1994. I appreciate your concern and desire to follow up on all materials relevant to radioactive fallout that was detected in North Dakota in the late 1950's and early 1960's.

As you know, the Coordination and Information Center in Las Vegas, Nevada, is the primary location where relevant data and information from field surveys and other investigations conducted by the Atomic Energy Commission, military organizations, and the Public Health Service is maintained. The Coordination and Information Center has already prepared a listing of all pertinent documents (enclosed) that they have on record, which refer to North Dakota. This should be an excellent starting point from which to determine the type of specific potential documentation you seek.

We have advised the Coordination and Information Center of your interest in these documents. Once you have had an opportunity to review the enclosure and determine what specific documents you will need, you should direct your request to the Manager, Department of Energy Nevada Operations Office at the following address:

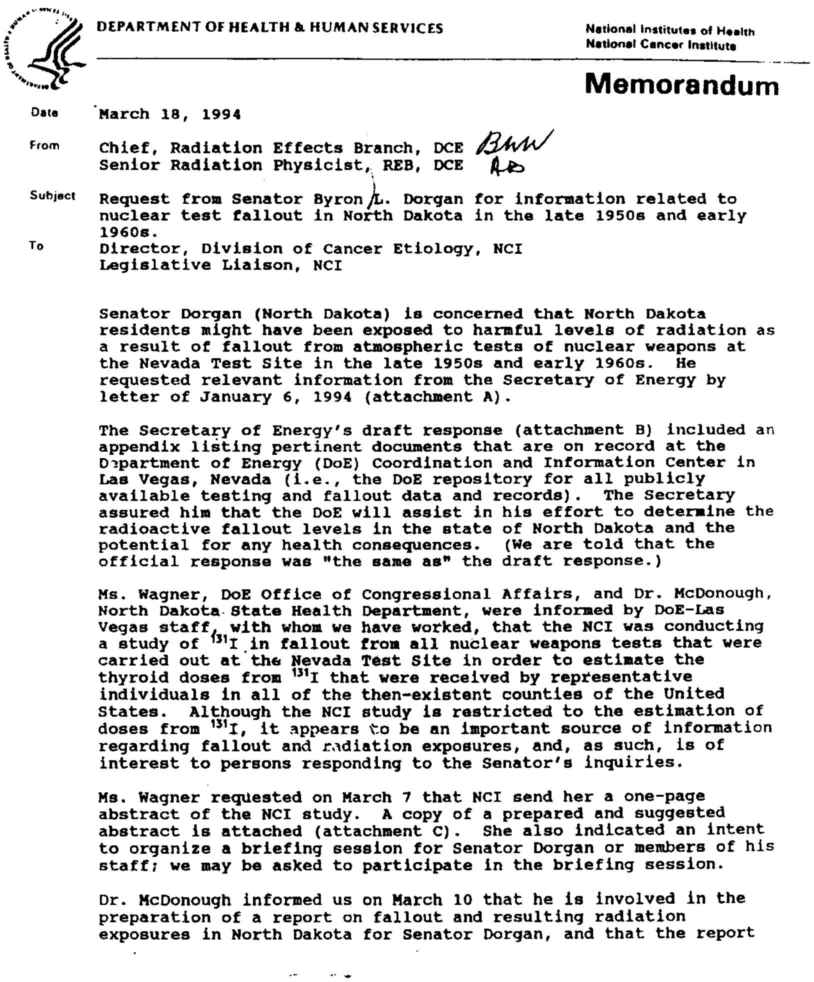
Mr. Nick C. Aquilina, Manager
Nevada Operations Office
U.S. Department of Energy
P.O. Box 98518
Las Vegas, Nevada 89193-8518

The Department will gladly assist you in the effort to determine the radioactive levels in the state of North Dakota and the potential for any health consequences.

Sincerely,

Hazel R. O'Leary

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date March 18, 1994

From Chief, Radiation Effects Branch, DCE
Senior Radiation Physicist, REB, DCE

Subject Request from Senator Byron L. Dorgan for information related to nuclear test fallout in North Dakota in the late 1950s and early 1960s.

To Director, Division of Cancer Etiology, NCI
Legislative Liaison, NCI

Senator Dorgan (North Dakota) is concerned that North Dakota residents might have been exposed to harmful levels of radiation as a result of fallout from atmospheric tests of nuclear weapons at the Nevada Test Site in the late 1950s and early 1960s. He requested relevant information from the Secretary of Energy by letter of January 6, 1994 (attachment A).

The Secretary of Energy's draft response (attachment B) included an appendix listing pertinent documents that are on record at the Department of Energy (DoE) Coordination and Information Center in Las Vegas, Nevada (i.e., the DoE repository for all publicly available testing and fallout data and records). The Secretary assured him that the DoE will assist in his effort to determine the radioactive fallout levels in the state of North Dakota and the potential for any health consequences. (We are told that the official response was "the same as" the draft response.)

Ms. Wagner, DoE Office of Congressional Affairs, and Dr. McDonough, North Dakota State Health Department, were informed by DoE-Las Vegas staff, with whom we have worked, that the NCI was conducting a study of ^{131}I in fallout from all nuclear weapons tests that were carried out at the Nevada Test Site in order to estimate the thyroid doses from ^{131}I that were received by representative individuals in all of the then-existent counties of the United States. Although the NCI study is restricted to the estimation of doses from ^{131}I, it appears to be an important source of information regarding fallout and radiation exposures, and, as such, is of interest to persons responding to the Senator's inquiries.

Ms. Wagner requested on March 7 that NCI send her a one-page abstract of the NCI study. A copy of a prepared and suggested abstract is attached (attachment C). She also indicated an intent to organize a briefing session for Senator Dorgan or members of his staff; we may be asked to participate in the briefing session.

Dr. McDonough informed us on March 10 that he is involved in the preparation of a report on fallout and resulting radiation exposures in North Dakota for Senator Dorgan, and that the report is to be completed within two months. Dr. McDonough asked if we could share with him the information related to thyroid doses received by representative individuals in North Dakota that is contained in the NCI report under preparation. He was informed that this information is still preliminary; nevertheless, he requested copies of the relevant information and stated that he would treat it as such.

We have referred both Ms. Wagner and Dr. McDonough to the NCI Legislative Liaison Office.

Attachments

ATTACHMENT C

18 March 1994

THE NCI REPORT ON "EXPOSURE OF THE AMERICAN PEOPLE TO, AND THYROID DOSES FROM, IODINE-131 FROM NEVADA ATMOSPHERIC BOMB TESTS"

Section 7(a) of Public Law 97-414 in part directs the Secretary of Health and Human Services to (1) "conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests," and (2) "estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout." The National Cancer Institute (NCI) was requested to respond to this mandate and a final report is in preparation.

The report provides estimates of human exposure to and thyroid doses from iodine-131 resulting from individual nuclear tests conducted at the Nevada Test Site. Thyroid dose estimates are given for representative individuals in various age groups, including *in utero*, and both sexes, residing in each county of the contiguous United States. The study suggests that there were large variations in thyroid dose from one individual to another, depending primarily upon the county of residence at the time of each test, the age of the individual at the time of exposure, and the origin and amount of milk consumed.

About 100 of the nuclear weapons tests carried out at the Nevada Test Site (NTS) resulted in off-site detection of radioactive materials. These tests released about 150 million curies of iodine-131 into the atmosphere, most of which were released in 1952, 1953, and 1957. Radioiodine was deposited across the United States, with the highest values immediately downwind of the NTS and the lowest values on the west coast. In the eastern part of the country, most of the deposited iodine-131 was associated with rainfall, while in the more arid west, dry deposition prevailed. Because iodine-131 decays with an 8-day half-life, exposure to the released iodine-131 occurred primarily during the first two months following a test.

For most people, the major exposure route was via the ingestion of cows' milk contaminated as the result of iodine-131 deposited on pasture grasses. Historical measurements of deposited radioactivity and of the daily amounts of rainfall across the United States were used as the basis for the dose calculations whenever possible. Data regarding the consumption of pasture grasses by cows and the transfer of iodine-131 to milk were reconstructed and used to estimate concentrations of iodine-131 in milk. Milk production, processing, and distribution patterns in the 1950s were used to estimate the amount of iodine-131 in the cows' milk available for human consumption throughout the country. Finally, milk consumption rates, based upon diet surveys, were used to estimate the amounts of iodine-131 ingested by representative individuals in each county.

The exposure of people to iodine-131 resulting from the inhalation of contaminated air and the ingestion of contaminated leafy vegetables, goats' milk, cottage cheese, and eggs also was analyzed, but in less detail, as the thyroid doses from iodine-131 resulting from these exposure routes are, for most people, much lower than those due to the consumption of cows' milk.

NORTH DAKOTA
STATE DEPARTMENT OF HEALTH
AND CONSOLIDATED LABORATORIES
State Capitol
600 E. Boulevard Avenue
Bismarck, ND 58505-0200
Fax # 701-224-4727 TDD 701-224-2068

PREVENTIVE HEALTH SECTION

April 6, 1994

Dorothy Tisevich
Director of Legislation
and Congressional Activities
National Cancer Institute
National Institutes of Health
Building 31, Room 11A-23
Bethesda, MD 20892

Dear Ms. Tisevich:

The North Dakota State Department of Health and Consolidated Laboratories is requesting I^{131} data for North Dakota counties from the nuclear fallout studies. I have been in contact with Dr. Bouville and we have discussed a preliminary data request. The data requested includes the five tests mentioned by Senator Dorgan in his letter to the Department of Energy and the cumulative I^{131} doses by county and age class. We are also requesting the cumulative Utah county data so a comparison can be made regarding health effects.

This information will be of assistance in evaluating possible health effects from nuclear fallout in North Dakota. If you have any questions concerning this request, please feel free to give me a call at 701/224-2493.

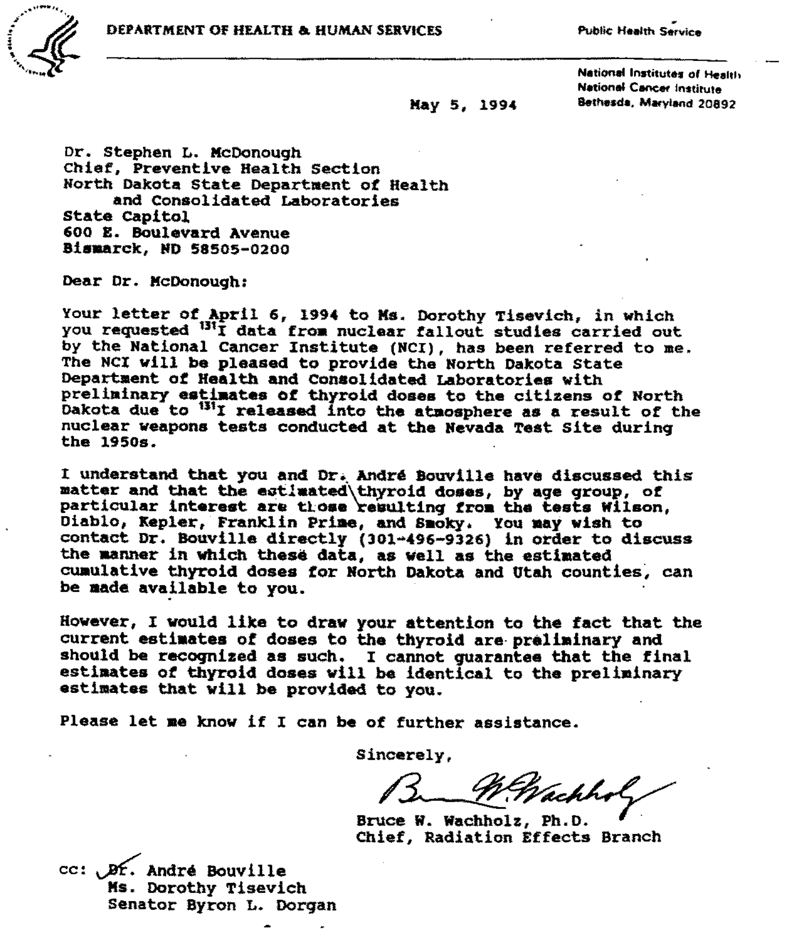
Sincerely yours,

Stephen L. McDonough, M.D.
Chief, Preventive Health Section

rn

c: ✓Dr. Andre Bouville
Senator Byron L. Dorgan

Disease Control 701-224-2378 | Health Promotion and Education 701-224-2367 | Maternal and Child Health 701-224-2493 | Microbiology 701-221-5262



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

May 5, 1994

Dr. Stephen L. McDonough
Chief, Preventive Health Section
North Dakota State Department of Health
and Consolidated Laboratories
State Capitol
600 E. Boulevard Avenue
Bismarck, ND 58505-0200

Dear Dr. McDonough:

Your letter of April 6, 1994 to Ms. Dorothy Tisevich, in which you requested ^{131}I data from nuclear fallout studies carried out by the National Cancer Institute (NCI), has been referred to me. The NCI will be pleased to provide the North Dakota State Department of Health and Consolidated Laboratories with preliminary estimates of thyroid doses to the citizens of North Dakota due to ^{131}I released into the atmosphere as a result of the nuclear weapons tests conducted at the Nevada Test Site during the 1950s.

I understand that you and Dr. André Bouville have discussed this matter and that the estimated thyroid doses, by age group, of particular interest are those resulting from the tests Wilson, Diablo, Kepler, Franklin Prime, and Smoky. You may wish to contact Dr. Bouville directly (301-496-9326) in order to discuss the manner in which these data, as well as the estimated cumulative thyroid doses for North Dakota and Utah counties, can be made available to you.

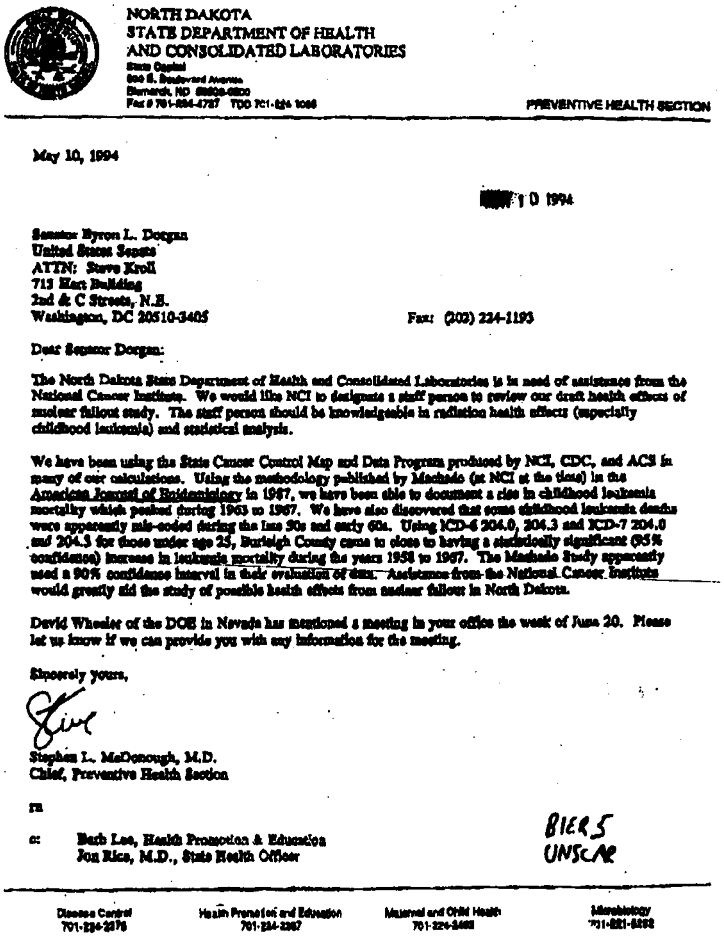
However, I would like to draw your attention to the fact that the current estimates of doses to the thyroid are preliminary and should be recognized as such. I cannot guarantee that the final estimates of thyroid doses will be identical to the preliminary estimates that will be provided to you.

Please let me know if I can be of further assistance.

Sincerely,

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

cc: Dr. André Bouville
Ms. Dorothy Tisevich
Senator Byron L. Dorgan



NORTH DAKOTA
STATE DEPARTMENT OF HEALTH
AND CONSOLIDATED LABORATORIES
State Capitol
600 E. Boulevard Avenue
Bismarck, ND 58505-0200
Fax # 701-224-4727 TDD 701-224 1088

PREVENTIVE HEALTH SECTION

May 10, 1994

[redacted] 1 0 1994

Senator Byron L. Dorgan
United States Senate
ATTN: Steve Kroll
713 Hart Building
2nd & C Streets, N.E.
Washington, DC 20510-3405

Fax: (202) 224-1193

Dear Senator Dorgan:

The North Dakota State Department of Health and Consolidated Laboratories is in need of assistance from the National Cancer Institute. We would like NCI to designate a staff person to review our draft health effects of nuclear fallout study. The staff person should be knowledgeable in radiation health effects (especially childhood leukemia) and statistical analysis.

We have been using the State Cancer Control Map and Data Program produced by NCI, CDC, and ACS in many of our calculations. Using the methodology published by Machado (at NCI at the time) in the American Journal of Epidemiology in 1987, we have been able to document a rise in childhood leukemia mortality which peaked during 1963 to 1967. We have also discovered that some childhood leukemia deaths were apparently mis-coded during the late 50s and early 60s. Using ICD-6 204.0, 204.3 and ICD-7 204.0 and 204.3 for those under age 25, Burleigh County came to close to having a statistically significant (95% confidence) increase in leukemia mortality during the years 1958 to 1967. The Machado Study apparently used a 90% confidence interval in their evaluation of data. Assistance from the National Cancer Institute would greatly aid the study of possible health effects from nuclear fallout in North Dakota.

David Wheeler of the DOE in Nevada has mentioned a meeting in your office the week of June 20. Please let us know if we can provide you with any information for the meeting.

Sincerely yours,

Steve

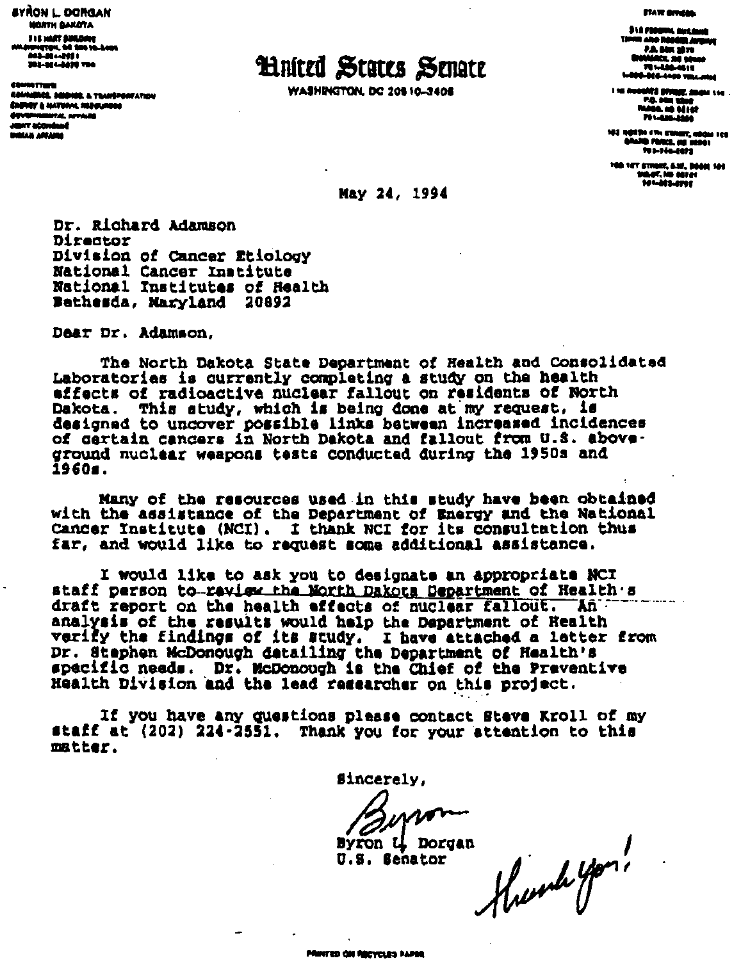
Stephen L. McDonough, M.D.
Chief, Preventive Health Section

ra

c: Barb Lee, Health Promotion & Education
Jon Rice, M.D., State Health Officer

BIER 5
UNSCAR

Disease Control	Health Promotion and Education	Maternal and Child Health	Microbiology
701-224-2378	701-224-2367	701-224-2493	701-221-6292



BYRON L. DORGAN
NORTH DAKOTA

United States Senate
WASHINGTON, DC 20510-3406

May 24, 1994

Dr. Richard Adamson
Director
Division of Cancer Etiology
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20892

Dear Dr. Adamson,

The North Dakota State Department of Health and Consolidated Laboratories is currently completing a study on the health effects of radioactive nuclear fallout on residents of North Dakota. This study, which is being done at my request, is designed to uncover possible links between increased incidences of certain cancers in North Dakota and fallout from U.S. above-ground nuclear weapons tests conducted during the 1950s and 1960s.

Many of the resources used in this study have been obtained with the assistance of the Department of Energy and the National Cancer Institute (NCI). I thank NCI for its consultation thus far, and would like to request some additional assistance.

I would like to ask you to designate an appropriate NCI staff person to review the North Dakota Department of Health's draft report on the health effects of nuclear fallout. An analysis of the results would help the Department of Health verify the findings of its study. I have attached a letter from Dr. Stephen McDonough detailing the Department of Health's specific needs. Dr. McDonough is the Chief of the Preventive Health Division and the lead researcher on this project.

If you have any questions please contact Steve Kroll of my staff at (202) 224-2551. Thank you for your attention to this matter.

Sincerely,

Byron

Byron L. Dorgan
U.S. Senator

Thank you!

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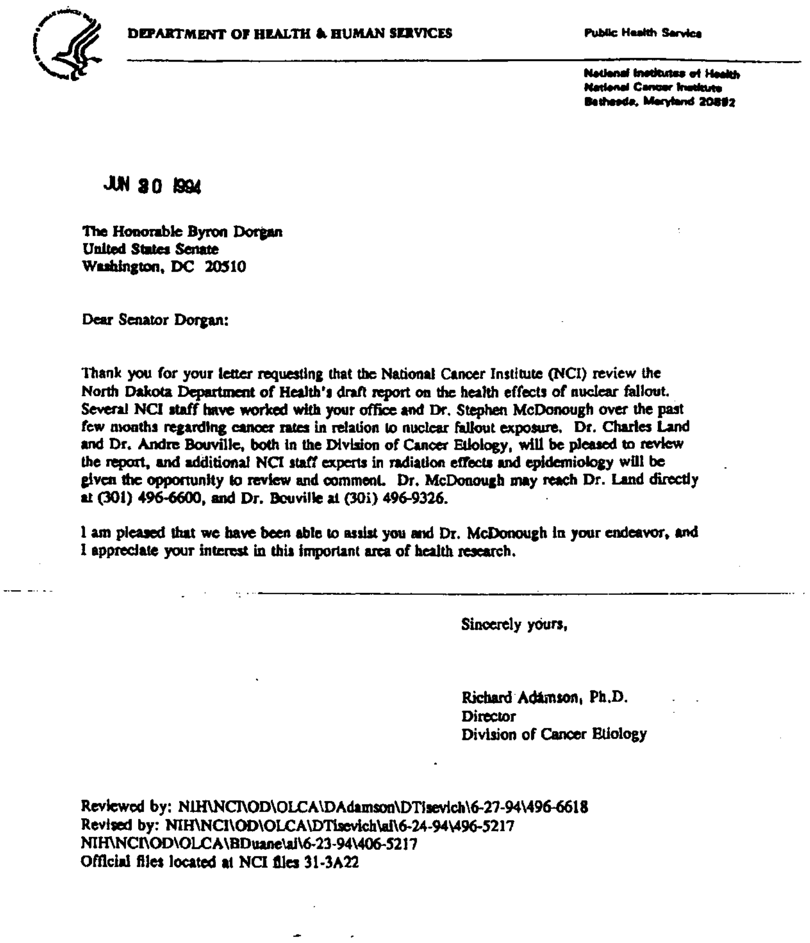

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

JUN 30 1994

The Honorable Byron Dorgan
United States Senate
Washington, DC 20510

Dear Senator Dorgan:

Thank you for your letter requesting that the National Cancer Institute (NCI) review the North Dakota Department of Health's draft report on the health effects of nuclear fallout. Several NCI staff have worked with your office and Dr. Stephen McDonough over the past few months regarding cancer rates in relation to nuclear fallout exposure. Dr. Charles Land and Dr. Andre Bouville, both in the Division of Cancer Etiology, will be pleased to review the report, and additional NCI staff experts in radiation effects and epidemiology will be given the opportunity to review and comment. Dr. McDonough may reach Dr. Land directly at (301) 496-6600, and Dr. Bouville at (301) 496-9326.

I am pleased that we have been able to assist you and Dr. McDonough in your endeavor, and I appreciate your interest in this important area of health research.

Sincerely yours,

Richard Adamson, Ph.D.
Director
Division of Cancer Etiology

Reviewed by: NIH\NCI\OD\OLCA\DAdamson\DTisevich\6-27-94\496-6618
Revised by: NIH\NCI\OD\OLCA\DTisevich\al\6-24-94\496-5217
NIH\NCI\OD\OLCA\BDuane\al\6-23-94\406-5217
Official files located at NCI files 31-3A22

KFD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

MEMORANDUM

Date: September 27, 1994

From: Chief, Radiation Effects Branch, CPCP, DCE

To: Legislative Liaison, NCI

Through: Acting Director, DCE, NCI

Subject: Response to Congressional Inquiry

Sen. Dorgan previously has contacted NCI requesting assistance to the State of North Dakota with respect to radioactive fallout from the Nevada Test Site. (See Attachment A for background correspondence.) Dr. Andre Bouville has reviewed and commented upon the documents requested by the Senator per Dr. Adamson's reply to the Senator.

Dr. Bouville's response to the Senator's request (see Attachment B) is provided for your review and/or concurrence.

Bruce W. Wachholz, Ph.D.

Concurrence: ____________________

Nonconcurrence: ____________________

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

September 19, 1994

Dr. Stephen L. McDonough
Chief, Preventive Health Section
North Dakota State Department of Health
and Consolidated Laboratories
State Capitol
600 E. Boulevard Avenue
Bismarck, ND 58505-0200

Dear Dr. McDonough:

I think that you have done a remarkable job of assembling most of the available information on fallout in North Dakota resulting from nuclear weapons tests. It would be helpful, however, to consult a specialist in radiation protection in the preparation of the final version of the report in order to improve the interpretation of the fallout data that you have assembled and to assist in the editorial style (especially with the units, quantities, and concepts used in radiation protection) of the report.

It seems clear that the ^{90}Sr levels in milk that were measured in the late 1950s and early 1960s generally were somewhat higher in North Dakota than in other areas of the United States where the amount of ^{90}Sr deposition on the ground was very similar. However, the reasons for those enhanced values are less clear. In any case, the resulting radiation doses are quite small, even in comparison to the doses from natural background. My main comments on your draft report are that: (1) you do not provide enough information on the radiation doses that were received by the populations of North Dakota from the nuclear weapons tests, (2) the structure of Chapter V (Nuclear Fallout in North Dakota) is not logical, so that this Chapter is very difficult to read, and (3) much information is given without a proper scientific reference.

You will find enclosed my detailed comments as well as suggested changes, most of which are of an editorial nature; they are presented in the sequence of your report. My comments are limited to the sections of the document that cover fallout, environmental releases of radionuclides, and radiation doses. I understand that Dr. Charles Land, also from the National Cancer Institute, has sent you comments on biology and on the health effects resulting from nuclear fallout.

Sincerely yours,

André Bouville
Senior Radiation Physicist

Copy: Ann E. Duane
Charles Land
Bruce W. Wachholz

August 30, 1994
André Bouville

COMMENTS ON:
"DOWNWIND IN NORTH DAKOTA: AN UNCERTAIN LEGACY"

- Page 1, bullet 4: I would replace the second line with: "measured concentrations of Strontium-90 in the United States."
- Page 3, first paragraph under IV. A.: replace "though" with "thought."
- Page 3, next-to-last paragraph, line 1: insert "associated with nuclear fallout" after "radiation."
- Page 3, next-to-last paragraph, line 2: delete "neutrons, protons."
- Page 3, last paragraph: replace "proteins" with "protons."
- Page 4, line 6 (and elsewhere): replace "Sr^{90}" with "^{90}Sr."
- Page 4, third paragraph: could be deleted (neutrons and protons do not play a role in the type of fallout that is considered in the report; as indicated correctly in para 5 of this page, only α, β, and γ are important in nuclear fallout).
- Page 4, fourth paragraph: replace "parcels of light" with "electromagnetic waves."
- Page 4, last paragraph to page 6, third paragraph: this description of radiation doses from various sources is important as it puts the doses from nuclear fallout in perspective. I think that this section would be improved if you: (1) separated clearly the natural sources of radiation (cosmic rays and terrestrial) from the manmade sources of radiation (medical, fallout, nuclear power, etc.), (2) indicated that the doses from natural sources vary from one location to another, but are relatively constant with time, whereas the doses from manmade sources depend on the magnitude and timing of the practice (for example, the doses from fallout were higher in the 1960s than they are now), and (3) explained that, in this section, the radiation exposures are expressed in terms of effective doses (unit: sievert), which combine the absorbed doses received by all organs and tissues of the body and weights them according to the radiosensitivity of those organs and tissues and to the type of radiation that is responsible for the dose. The effective dose permits a comparison of the radiation exposures from various sources to be made and is believed to represent the whole radiation risk

received by the exposed populations.

- Page 7, last 3 lines, and page 8, first 2 lines: I would replace with: "dose. The equivalent dose to the tissue considered (unit: sievert) is the product of the absorbed dose (unit: gray) by the radiation-weighting factor. For low-LET radiation like beta particles and gamma radiation, the radiation-weighting factor is generally assumed to be equal to 1, so that the equivalent dose and the absorbed dose have the same numerical values. For high-LET radiation like alpha particles, the radiation-weighting factor is greater than 1; for alpha particles, the radiation-weighting factor is generally assumed to be equal to 20, so that the numerical value of the equivalent dose is 20 times that of the absorbed dose [ICRP Publication 60. 1990 Recommendations of the International Commission on Radiological Protection. Annals of the ICRP, Vol. 21, No. 1-3; 1990]."
- Page 8, last two lines: I would replace "I^{131}" with "^{131}I" or with "I-131."
- Page 11, first line under B: I would replace "the atom" with "the nucleus of an atom."
- Page 11, second line under B: I would replace "two atoms" with "two nuclei."
- Page 11, last paragraph: I would replace with: "The atomic weight is the sum total of neutrons and protons in the nucleus of an atom. The atomic weight is often added to the name of the element, or to its symbol, particularly for radioactive products (for examples: Strontium-90 or Sr-90, Iodine-131 or I-131, Cesium-137 or Cs-137, Uranium-235 or U-235)."
- Page 12, first line: I would replace "Atoms" with "Elements."
- Page 12, lines 3 to 5: I would replace with: "Isotopes of an element have the same number of protons in the nucleus but different numbers of neutrons. For example, the common form of hydrogen has a nucleus with one proton and no neutron; a rare isotope of hydrogen, called deuterium (H-2), has one proton and one neutron; an even rarer isotope of hydrogen, called tritium (H-3) has one proton and two neutrons)."
- Page 13, third line before the end: I would replace "northern" with "temperate."
- Page 16, lines 3 and 4: I would replace "as more stable atoms form" with "as more fission fragments decay into less radioactive products or into stable forms."
- Page 16, third paragraph, line 1: I would replace "3.7 of

radioactivity a" with "3.7% of radioactivity at."

- Page 16, third paragraph, line 3: I would replace "Strontium-90 (Y-90)" with "Strontium-90, together with its decay product Yttrium-90."
- Page 16, third paragraph, line 4: I would replace "Cesium-137 (Ba-137)" with "Cesium-137, together with its decay product Barium-137m."
- Page 16, between third and fourth paragraphs: I would insert a short review of what is known about the doses from nuclear fallout. This short review would describe the relative importance of the various fission products with respect to dose and would also discuss the relative importance of internal irradiation versus external irradiation. This would explain why you plan to discuss specifically Sr-90, I-131, and Cs-137 in the following pages.
- Page 16, fourth paragraph, line 1: I would replace "radiative" with "radioactive."
- Page 16, fourth paragraph: the diagram needs to be cleaned up and introduced.
- Page 17, line 5: a better value for the biological half-life of Cs-137 in the body would be: about 100 days.
- Page 18, sections D and E: I assume that sections on I-131 and Cs-137 will be prepared according to the format used for Sr-90.
- Page 18, chapter V: I have problems with the organization of this Chapter. It seems to me that you want to: (1) show that nuclear fallout occurred in North Dakota, (2) present the available information on the levels of important radionuclides in the environment resulting from fallout, and (3) estimate the doses that the populations from North Dakota received from fallout. In Section A, History of Nuclear Tests, I would only keep the general history of nuclear testing and a description of the tests that resulted in nuclear fallout over North Dakota. With respect to the levels of important radionuclides in the environment, I would keep in mind that the most important contributions to the radiation doses from nuclear fallout arise from: (1) external irradiation due to radionuclides deposited on the ground, and (2) internal irradiation due mainly to ingestion of radionuclides, essentially with milk, but also with other foodstuffs. Accordingly, I would have a Section on "Radioactivity deposited on the ground" (in which I would include most of the information that you give in Section A), followed by Sections on "Radioactivity in Cow's Milk", "Radioactivity in Other

Foodstuffs", and "Radioactivity in Human Bones", Finally, a Section on the "Doses to the Populations of North Dakota from Nuclear Fallout" would be based on the contents of the preceding Sections. Any material related to health effects, such as what is presented on page 34, would be discussed in Chapter VI.

- Page 19, line 6: accepted values for the yields of Hiroshima and Nagasaki bombs are 15 and 21 kt, respectively [Roesch, W.C., ed. US - Japan Joint Reassessment of Atomic Bomb Radiation Dosimetry in Hiroshima and Nagasaki. Final Report. The Radiation Effects Research Foundation; Hiroshima, Japan; 1987.]

- Page 20, lines 7 to 11: I would delete the end of the paragraph, starting from "Later, the." As far as I could tell, this information was not used later on in the document.

- Page 20, fifth paragraph, line 3: I would replace "high life" with "half-life." [In addition, I think that this paragraph is in the wrong place and should be moved up to page 16.]

- Page 21, fourth paragraph, line 2: Replace "Eisenbad" with "Eisenbud." Also, you should be consistent about the manner in which you abbreviate "disintegrations per minute per square foot in a day"; I would use "dis/(min x ft^2) in a day."

- Page 24, title: Replace "Plumbobb" with "Plumbbob."

- Page 31, line 9: According to a personal communication from Ed Hardy and Harold Beck (DoE's Environmental Measurements Laboratory in New York), Pfeiffer's estimation that 22 mCi ^{90}Sr/mi^2 fell in Fargo in July 1957 may have been derived from an erroneous piece of data from the AEC that was reported in the 1959 Congressional Hearings on Fallout. Subsequently, the AEC reported that the recomputation of the ^{90}Sr fallout on July 16 at Fargo from the Diablo shot in the Plumbbob series led to a ^{90}Sr deposit of only about 1 mCi/mi^2 (0.5 mCi/km^2) [Knapp, H.A. The contribution of short-lived isotopes and hot spots to radiation exposure in the United States from nuclear test fallout. Fallout Studies Branch, USAEC Report TID-8527, 6 June 1960]. Based on more recent studies of gummed film efficiencies, assuming that a heavy rainfall scavenged the Diablo cloud over Fargo, the 90Sr deposit could have been as high as 5-8 mCi/mi^2 (2-3 mCi/km^2). It is unfortunate that the Fargo and Williston gummed film data related to the Plumbbob series cannot be located so that a re-evaluation of the deposition of individual radionuclides, such as was carried out for available gummed film data [Beck, H.L. Estimates of fallout from Nevada weapons testing in the United States based on gummed film monitoring data. USDOE report EML-433; 1984]; [Beck, H.L., Helfer, I.K., Bouville, A. and Dreicer, M.

Estimates of fallout in the continental U.S. from Nevada weapons testing based on gummed film monitoring data. Health Phys. 59:565-576; 1990] could lead to a more definite answer to this question.

- Page 31, fourth paragraph and elsewhere: The units should be checked and made consistent. As noted later on (page 35), "μμ or micro-micro" should be replaced with "p or pico." Also, "c" or "C" are often used in this text instead of "Ci" (for curie). In addition, it would be helpful to use always the same unit for deposited activity, for example, mCi per km^2. It is to be noted that the curie is an old unit and that the new unit is the becquerel; however, it could be very confusing to switch to becquerels at this stage.

- Page 32, last paragraph, first three lines: for a given deposition on the ground of ^{131}I, the resulting thyroid doses may vary by orders of magnitude depending, among other factors, on the type of fallout, agricultural practices, amount, type and origin of milk consumed, and thyroid mass of the individual considered. Tamplin's dose estimate seems to be very high and is likely to apply to extreme conditions.

- Page 32, last line: replace "Department of Energy (DOE)" with "National Cancer Institute (NCI)."

- Page 33, first line: the end of the sentence could be replaced with: "estimates that the median thyroid doses received by infants who lived in Cass county, where Fargo is located, and who drank fresh milk from family cows at the time of the Diablo shot in July 1957 were about 2 rad; those infants represent a high-exposure group; at the other end of the scale, much lower doses of about 0.02 rad are estimated to have been received by the group of female adults who consumed no fresh cows' milk and obtained their ^{131}I intake from consumption of other contaminated foodstuffs, such as leafy vegetables or eggs, and from inhalation. The average thyroid dose that was received by the population of Cass county as a result of the test Diablo is currently estimated by the NCI to be 0.25 rad. It should be noted that these thyroid dose estimates are fraught with very large uncertainties, partly due to the fact that fallout data specific for the test Diablo are not available for North Dakota."

- Page 33, first paragraph, last sentence: Could be replaced with: "Thus, the actual 131I and 90Sr fallout in North Dakota from individual tests of the Plumbbob series is not known, although it can be crudely estimated from fallout data from other States."

- Page 33, second paragraph, last line: replace "Plowshore" with "Plowshare."

- Page 33, sixth paragraph: replace "band" with "ban."

- Page 33, beginning of section C: I would indicate early on that the strontium unit or sunshine unit (SU) is equal to one picocurie of ^{90}Sr per gram of calcium (pCi/gCa). In any case, it may be confusing for the reader to be confronted with two units for the same quantity. Also, it would be worth noting that, since there is about 1.1. gram of calcium per litre of milk, one picocurie per liter of milk is equal to 0.9 picocurie per gram of calcium.

- Page 37, last paragraph and last Table: (1) check the unit "mc/m^2" (probably mCi/mi^2"), and (2) could be moved to the Section on deposition.

- Page 38, fifth paragraph, last sentence: Should be removed. In fact, fallout occurred over most parts of the United States in 1951, 1952, 1953, 1955, 1957, and 1958 from tests conducted at the Nevada Test Site; it also occurred over all of the United States from 1952 through at least 1980 as a result of tests conducted at other sites.

- Page 38, last paragraph, second and third sentences: the statement that North Dakota received more fallout of stratospheric origin than other states should be demonstrated and referenced. DOE's data [Ed Hardy and Harold Beck, personal communication] show that the deposition of ^{90}Sr at Williston, ND, during the 1960s was less than in New York, NY.

- Page 41, second paragraph: This paragraph should be redrafted if it cannot be demonstrated that the deposition of ^{90}Sr in North Dakota in the 1960s was much higher than in other parts of the United States. Regarding the the soil to milk transfer of ^{90}Sr, it may be that North Dakota soils are both more efficient in passing ^{90}Sr into the foodchain and in migrating it into deeper layers of soil, so that, for a given deposition of ^{90}Sr in North Dakota and in other areas of the U.S., the levels of ^{90}Sr in milk are higher for a few years after deposition and later decrease to lower values than in other areas of the U.S.

- Page 49, third paragraph, last sentence: It seems to me that the data presented in Figure 7 do not support the statement that you make in this sentence. Figure 7 shows that there is a wide variability in the ratios of the 90Sr concentrations between soil and milk. The average milk-to-soil ratio in the 12 locations that are considered is 0.5. The ratio in Mandan is greater than the average by a factor of 2.4, but there are also locations where the ratios are lower than the average by a factor of 2.4 or more (Des Moines, Philadelphia, Los Angeles, and Salt Lake City). The ratio in Mandan is no more abnormal than the ratios observed in those 4 locations, and is likely to be due to the variability in the transfer of 90Sr from soil to milk.

- Page 51, section D: The levels of ^{90}Sr in human bone are expected to be correlated to those in diet. Since milk is an important contributor to the ^{90}Sr content in diet, it is normal to measure ^{90}Sr levels in human bone that are higher than the U.S. average, at least during the few years following the major episodes of fallout.

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date January 3, 1995

From Chief, Radiation Effects Branch, CPCP, DCE

Subject Telephone Conversation with Dr. Steven McDonough, North Dakota State Department of Health, Author of "Downwind in North Dakota: An Uncertain Legacy"

To Legislative Liaison, NCI
Through: Acting Director, DCE

Last week I tried unsuccessfully to speak with Dr. McDonough as a followup to our meeting on December 16 with him and with Senator Byron Dorgan (ND). (I could not do so during the week of December 19-23 because of laryngitis.) The intent was to offer to send specific scientific comments on either (a) his draft report that was the subject of the December 16 meeting, or (b) any revised draft report that may evolve as a result of the discussion on December 16. It also was my intent to followup on the general invitation for him to visit with NCI staff.

This morning I finally spoke with Dr. McDonough and learned that:

1. Senator Dorgan held a press conference in Bismarck last week, the subject of which was Dr. McDonough's fallout and health effects report.

2. State news media were present at the conference but no reference was made to national media.

3. The findings were placed in a context that was "not alarming" and it was pointed out that a small number of children might have been affected, but that this is not known for sure, that the numbers are mathematical estimates and are quite uncertain.

4. They have received "only a few letters" as a result of the press conference.

5. The fallout document currently is in press and no changes were made (other than typos) regarding the text, tone or content of the report as a result of the December 16 meeting, and while he personally would appreciate detailed scientific comments, they are too late to incorporate into the report. He stated that he was anxious to terminate that particular effort and move on to other things.

6. With one exception he does not see any further interest in this issue and does not see Senator Dorgan pursuing it (e.g., no Congressional hearings), although he pointed out that he could not speak for the Senator.

7. The one exception probably will be a request to NCI from Senator Dorgan to review existing data to assess childhood leukemia in the upper midwest (MT, ND and WY were mentioned) during the 1960s to see if there was even a non-significant increase. (According to him, "this might be a one-day effort by someone" at NCI.)

Dr. McDonough expressed much appreciation for the December 16 meeting and for the opportunity to speak with experts in the field of fallout studies.

He also indicated that he did not see the usefulness of meeting with NCI or DOE staff unless this continued to be an issue requiring his involvement or unless he was in the area for other reasons.

He again mentioned that Keith Rogers, reporter for the Las Vegas Review Journal(?), may continue to explore the fallout issue.

I requested that he send us copies of his final report and of any articles resulting from the press conference, and he readily agreed to do so.

Although Dr. McDonough made many complimentary comments about NCI, he expressed mild surprise at the "lack of intellectual curiosity" by NCI staff that he perceived in the December 16 meeting with respect to levels of fallout and possible health consequences. He attributed this to the assumption that NCI staff looked at major exposed populations such as Japan and Chernobyl, while ND by comparison was almost insignificant, whereas he looked at ND expecting to see nothing and thought he observed the possibility of something.

We closed with mutual expressions of goodwill in the new year.

Bruce W. Wachholz, Ph.D.

cc: Dr. Boice
Dr. Bouville
Dr. Fraumeni
Dr. Land

ENERGY
RESEARCH
FOUNDATION

Frances Close
Board Chairwoman

Theodore K. Harris, Esq.
President

May 1, 1996

Tim Connor
Associate Director
S. 1016 Buena Vista Drive
Spokane, WA 99204

Dr. Richard Klausner
Director, National Cancer Institute
Building 31, Rm. 11A48
Bethesda, MD 20892

Dear Dr. Klausner:

I am writing on behalf of the Advisory Committee on Energy-Related Epidemiologic Research (ACERER) in the hope that you can assist our committee. As you may know, the ACERER was appointed by then-Secretary of Health and Human Services Louis Sullivan in 1992 to advise the Secretary on setting the research agenda and conducting research as outlined in the December 1990 Memorandum of Understanding between the Department of Health and Human Services (HHS) and the Department of Energy (DOE).

The HHS/DOE MOU sets forth a comprehensive program of research in the area of ionizing radiation exposure and potential health effects. This program includes, but is not limited to, new and continuing epidemiologic studies of workers at DOE facilities and the study of communities in the vicinity of these facilities. The Centers for Disease Control and Prevention (CDC) was assigned the lead role for this research program within HHS.

Over time, the Committee has reached the general conclusion that our role of advising the Secretary on research needs and priorities requires that we become more fully aware of the initiation, existence, and progress of other federally funded research activities involving radiation and human health. With this knowledge we believe we can better advise the Secretary on opportunities for cooperative endeavors and ways to maximize cost effectiveness of research funds in this area of health science. This view is reflected in the attached motion adopted at our April meeting in Santa Fe.

For that reason, I would like to request the following information with respect to NCI research activities involving studies of radiation exposure and health consequences:

- The title and general description of each project.

- The legislation or other mechanism by which it was initiated.

- The principal investigators, initiation date and status of the project.

Brian Costner, Director, 537 Harden Street, Columbia, SC 29205, 803/256-7298, fax: 803/256-9116
Tim Connor, Associate Director, S. 1016 Buena Vista Drive, Spokane, WA 99204, 509/838-4580, fax: 509/624-9188

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ATTACHMENT

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For your convenience, I am also attaching a copy of the ACERER charter and the 1990 MOU. Currently, a revised MOU is in the final stages of negotiation between the two agencies and should be available by the end of this year.

Again, I would much appreciate your assistance in providing the above information for our Committee.

Sincerely,

cc Dr. John Bagby, Chairman, ACERER
Dr. David Satcher, Director, Centers for Disease Control and Prevention

Whereas the DOE/HHS MOU has delegated a leadership role to HHS in the area of radiation health studies;

Whereas the CDC has taken the lead in addressing public health consequences of radioactive releases from nuclear facilities;

Whereas the Committee believes that enhanced federal collaboration and coordination is necessary to improve the quality and cost-effectiveness of federally funded radiation research;

Therefore let it be resolved-that CDC should work with DOE/ES&H and NCI to seek collaboration on all national and international activities in which results may complement informative needs of CDC (for sites at which dose reconstruction is ongoing or planned). Activities of particular interest would be:

1. the unpublished nationwide study of thyroid doses to the U.S. public from I^{131} released from the Nevada Test Site;

2. the thyroid disease/I^{131} dose reconstructions by NCI/LLNL/FHCRC for Ukraine and Bylorus, and Russia;

3. plutonium, strontium and I^{131} dose reconstruction for the Techa River, Chelyabinsk and the Mayak facility of Russia;

4. all other national and international activities that may produce results of value to CDC's dose reconstruction studies.

Energy Research Foundation

August 2, 1996

From: Tim Connor, ERF

Phone (509) 838-4580
Fax (509) 624-9188

To: Nancy Burgoyne, National Cancer Institute

(301) 402-0338

Ms. Burgoyne--The attached 6 pages are the May 1st letter to Dr. Klausner, a copy of the Advisory Committee's resolution from April, and a copy of the Committee charter. I have not attached the Memorandum of Understanding referenced in the letter because it is a much longer document. If it would be useful to send the MOU just let me know and I'll fax you the most recent version I have.

Again, I'd appreciate it if someone can get back to me soon with a response or timeline for a response.

TC

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Executive Plaza North EPN 540
6130 Executive Blvd MSC 7398
Bethesda MD 20892-7398

September 11, 1996

Tim Connor
Associate Director
Energy Research Foundation
S. 1016 Buena Vista Drive
Spokane, WA 99204

Dear Mr. Connor:

In response to your request, enclosed please find a table of intramural radiation-related studies being conducted by the Division of Cancer Epidemiology and Genetics of the National Cancer Institute. We regret that our response to you has been delayed and hope that it meets the needs of the Advisory Committee on Energy-Related Epidemiologic Research.

Sincerely,

Joseph F. Fraumeni, Jr., M.D.
Director
Division of Cancer Epidemiology
and Genetics
National Cancer Institute

cc: Dr. Klausner
Dr. Sontag

Division of Cancer Epidemiology and Genetics
National Cancer Institute

Research Activities Involving Studies of Radiation Exposure and Health Consequences

Project Title	Principal Investigator(s)	Description	Start Date	Activity Level	Mechanism
Cancer Following bone marrow transplantation	Ms. R. Curtis	Cohort study of 20,109 patients who received total body irradiation	9/92	Active	National Cancer Act
Cancer risk in x-ray technologists	Ms. M. Doody	Cohort of 140,000 x-ray techs, biodosimetry, questionnaires	8/91	Active	National Cancer Act
Epidemiological studies of Mayak and Techa river cohorts	Dr. E. Ron	Cohort study of occupational and environmental exposure including about 45,000 people dosimetry	9/95	Active	National Cancer Act
Feasibility study of leukemia among Chernobyl cleanup workers	Dr. G. Beebe	Cohort study of cleanup workers including thyroid screening and biodosimetry	1992	Active	National Cancer Act
Childhood leukemia and electromagnetic fields	Dr. M. Linet	Case-control study of 600 leukemia patients and population controls	9/89	Active	National Cancer Act
Second malignant neoplasms following cancer of ovary and testis	Dr. L. Travis	Therapeutic radiation-induced second cancers and interaction with chemotherapy	10/95	Active	National Cancer Act
Cancer in navy Korean war veterans	Dr. F. Groves Dr. G. Beebe	Cohort of Navy radar workers exposed to microwave radiation	9/94	Active	National Cancer Act
Lung cancer and high levels of indoor radon	Ms. R. Kleinerman Dr. Jay Lubin	Case control study of 900 lung cancer patients and 1,800 population controls; radon measurements in all residences;	2/95	Active	National Cancer Act
Epidemiologic studies of atomic bomb survivors	Dr. C. Land	Multi-disciplinary studies of site-specific cancer risk in cohort of 120,000	9/92	Active	National Cancer Act

Project Title	Principal Investigator(s)	Description	Start Date	Activity Level	Mechanism
Cancer following long-term exposure to Thorotrast	Dr. L. Travis	Cancer risk in a cohort of about 2,000 Thorotrast exposed patients	5/92	Active	National Cancer Act
Indoor radon and lung cancer among women	Dr. M. Alavanja	Case-control study of lung cancer Radon measurements in residences	9/92	Active	National Cancer Act
Long-term follow-up of cancer risk in retinoblastoma patients	Ms. R. Kleinerman	Cohort of 1,500 patients; radiation and genetic interaction	9/82	Active	National Cancer Act
Long-term follow-up of cancer risk in tuberculosis patients	Dr. M. Alavanja	Cohort of 20,000 patients; multiple chest fluoroscopic exposure; dosimetry	9/79	Active	National Cancer Act
Cancer risk following nasopharyngeal radiation in childhood	Dr. C. Land	Cohort of 2,000 children who received therapeutic nasal irradiation; dosimetry	10/95	Active	National Cancer Act
Cancer risk following diagnostic radiation for scoliosis in childhood	Ms. M. Doody	Breast cancer risk in a cohort of 5,600	3/88	Active	National Cancer Act
Cancer risk following tonsillar irradiation in childhood	Dr. E. Ron	Cancer Incidence in a cohort of 4,300 patients dosimetry	4/89	Active	National Cancer Act
Case-control study of brain cancer	Dr. E. Hatch	Evaluation of Brain cancer and cellular telephone exposure	9/93	Active	National Cancer Act
Cancer risk following I-131 treatment for hyperthyroidism	Dr. E. Ron	Mortality after I-131 exposure	1984	Active	National Cancer Act
Cancer risk following radiotherapy for peptic ulcer	Ms. R. Kleinerman	Mortality after radiotherapy in 2,000 exposed patients and 2,000 nonexposed subjects	9/88	Active	National Cancer Act
Cancer incidence following diagnostic I-131 in Israel and Slovenia	Dr. E. Ron	Cohort of 45,000 patients from two countries	9/88	Active	National Cancer Act

Project Title	Principal Investigator(s)	Description	Start Date	Activity Level	Mechanism
Cancer incidence following radiotherapy for infertility in Israel	Dr. E. Ron	Cohort of 1,200 women	1986	Active	National Cancer Act
Dosimetry support for studies of radiation workers	Ms. M. Doody	Registry of 200,000 workers using records from a commercial dosimetry company	9/89	Active	National Cancer Act
Lung cancer in underground miners exposed to radon	Dr. J. Lubin	Pooled analysis of 11 miner cohorts	1991	Active	National Cancer Act

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Executive Plaza North 530
6130 Executive Blvd
Bethesda MD 20892

March 10, 1997

James M. Smith, Ph.D.
Chief, Radiation Studies Branch
Centers for Disease Control and Prevention
F-35
4770 Buford Highway NE
Atlanta, GA 30341-3724

Dear Dr. Smith:

Thank you for your inquiry on behalf of Dr. Richard J. Jackson, Director, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC) and the CDC Advisory Committee for Energy-Related Epidemiologic Research, regarding the status of the National Cancer Institute (NCI) assessment of exposure of the American people to Iodine-131 from atmospheric nuclear weapons tests conducted at the Nevada Test Site.

The technical component of the report is complete, and the text of the report has undergone several reviews and redrafts. We plan to publish the report during fiscal year 1997 and are presently investigating the most effective manner in which to make the full report available (which in hard copy is expected to approach or exceed one hundred thousand pages).

In the meantime, we have tried to be responsive to reasonable requests for information contained within the report pertaining to specific areas. For example, we met with Senator Byron Dorgan and representatives of the North Dakota State Department of Health and Consolidated Laboratories to discuss Iodine-131 fallout in North Dakota. Also, a member of the Advisory Committee, Dr. F. Owen Hoffman, Jr., requested Iodine-131 fallout information for areas in the vicinity of Oak Ridge, TN. In response to both of these requests, relevant data were provided to them.

You also requested a brief description of our cooperative studies in Belarus and Ukraine related to the Chernobyl nuclear power plant accident. The NCI, with additional financial support from the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC), is working with scientists and government authorities in Belarus and Ukraine to carry out long-term epidemiological studies of thyroid disease, especially cancer, among persons (1) who were under the age of 18 at the time of the accident, (2) who were exposed to fallout from the accident, and (3) whose thyroids were measured for radioactivity content during the weeks immediately following the accident. The cohorts are expected to consist of about 15,000 persons in Belarus and perhaps 50,000 persons in Ukraine. In addition to clinical and diagnostic tests conducted annually or biennially to assess thyroid anatomy and function, efforts are being made to reconstruct the doses to the thyroid that each subject received, mainly from the intake of radioactive iodine. Ultimately, it is expected that risk coefficients will be derived from these data.

NCI is cooperating also with Ukrainian scientists and authorities to investigate leukemia, lymphoma and other hematologic diseases among Ukrainian cleanup workers (i.e., "liquidators") who were at Chernobyl during 1986-1990. This study consists of two phases. Phase I will explore the feasibility of carrying out a long-term (i.e., perhaps 15 years) epidemiological study and will consist of investigations and introductory steps that relate to both the identification of a suitable cohort and the clinical, dosimetric and administrative procedures necessary to implement Phase II, the study itself. The intent of the study is to expand present knowledge both of the radiation dose- and time-response for leukemia in the low and moderate dose regions, and of the influence of dose rate on risk estimates.

Agreements to implement these three projects have been signed by the U.S. and by the Ministers of Health of Belarus and Ukraine, and financial agreements to support these projects have been agreed to by the NCI, DOE, and NRC.

I hope that the above responds adequately to your request.

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

9/25/97

Centers for Disease Control and Prevention
Advisory Committee on Energy-Related Epidemiologic Research
Requests for Information on I-131 Fallout Study
Major Actions

Background Documents

6/13/90	Letter from James Watkins, Secretary of Energy, to Louis Sullivan, Secretary of Health and Human Services, thanking him for agreeing to accept the management responsibility through CDC for the epidemiologic research studies at the DoE. Documents of this arrangement are attached to this letter.
12/90	Memorandum of Understanding (MOU) signed between DoE and HHS outlining the HHS role in managing and conducting energy-related analytic epidemiologic health research for DoE. This included the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of analytic epidemiologic studies of the following populations: workers at DoE facilities; residents of communities in the vicinity of DoE facilities; other persons potentially exposed to radiation; and persons exposed to potential hazards resulting from non-nuclear energy production and use.
2/28/94	CDC Advisory Committee chartered through 1996, which was established to make recommendations on strengthening the DoE research activities.
2/8/96	CDC Advisory Committee chartered through 1998.
4/??/96	CDC Advisory Committee adopted resolution that CDC should seek collaboration on all national and international activities in which results might complement information needs for CDC (for sites at which dose reconstruction is ongoing or planned). Activities of particular interest included "the unpublished nationwide study of thyroid doses to the US public from I-131 released from the Nevada Test Site..."
5/14/96	MOU between DoE and HHS signed, effective through the year 2000.

Requests for Information

5/1/96	Request from Mr. Connor on behalf of the Advisory Committee about NCI research activities involving studies of radiation exposure and health consequences. Request included: • 1990 Memorandum of Understanding • 1996 Charter for the Advisory Committee • April 1996 resolution
5/7/96	Document forwarded to Dr. Fraumeni for reply.
6/11/96	Response to Ms. Burgoyne to mail to Mr. Connor. As it is not the regular procedure to request that responses be returned to the OD for mailing, Ms. Burgoyne assumed she had been provided a copy and sent the original to Central Files. Response included research activities of the DCEG, as reported by Dr.

	Land; Radiation Effects Branch, DCB, activities were neither solicited nor included.
8/2/96	Fax from Mr. Connor inquiring about the response.
8/2/96	Mr. Connor's second request faxed to DCEG.
8/5/96	Note from Dr. Fraumeni to Ms. McClave, asking her to determine what happened to earlier effort to provide information. Memo from Ms. McClave to Dr. Fraumeni explaining that earlier response may have been sent to a letter provided "FYI" to Dr. Fraumeni. Notes from Ms. McClave describing phone call with Dr. Land, who expected to develop a response.
8/12/96	Copy of response sent to Ms. Burgoyne for mailing to Mr. Connor. Original sent to Central Files instead.
9/10/96	Dr. Land spoke with Mr. Connor, who noted that he had still not received the DCEG response.
9/11/96	Note from Ms. McClave to Dr. Fraumeni suggesting they send response directly to Mr. Connor. Response sent directly to Mr. Connor, apologizing for the delay in responding.
9/25/96	E-mail from Dr. Land to Ms. McClave requesting that a copy of DCEG's response be given to Dr. Wachcholz, who would append the letter to include activities of the Radiation Effects Branch, DCB. Copies handcarried that day.
2/27/97	CDC fax to Dr. Wachholz of the Advisory Committee Membership Roster.
3/10/97	Letter from Dr. Wachholz in response to a phone inquiry by Dr. Smith on behalf of Dr. Jackson, providing a written status update of the I-131 fallout report, stating plans to publish the report during FY 1997. Included a brief description of the studies in Belarus and Ukraine related to the Chernobyl nuclear power plant accident.
7/30/97	Letter from Dr. Smith to Dr. Wachholz thanking him for his willingness to meet with the Advisory Committee at its December meeting to brief it on the I-131 Fallout Report. Dr. Smith requested the complete data base as soon as possible.
8/5/97	Letter from Dr. Wachholz to Dr. Smith explaining that the information will be released October 1, 1997.
9/16/97	E-mail from Dr. Wachholz to Ms. Duane explaining his recollection of events.
9/18/97	Summary from Ms. McClave to Ms. Duane of DCEG actions regarding inquiry.
9/18/97	Items from CDC sent to Dr. Austin (forward to Ms. Duane 9/22/97): • Original MOU • Current MOU • Current Advisory Committee Charter • May 1997 Advisory Committee Membership List • Copies of Mr. Connor's inquiry, DCEG's 9/11/96 response, and Dr. Wachholz' 3/10/97 letter.
9/22/97	E-mail from Dr. Austin describing her conversation with Dr. Falk at CDC, including a copy of Dr. Jackson's email after their conversation.

Sometime after this, Dr. Austin received an apology from Dr. Jackson for the "accusation" that NCI had "refused" invitations to discuss the study. Dr. Jackson could find no record that invitations were issued. This corroborated NCI's assertion that no invitations were received.

Austin, Faye

From: Wachholz, Bruce W.
Sent: Tuesday, September 16, 1997 11:49 AM
To: Duane, Betsy
Cc: Austin, Faye
Subject: Your inquiry re "I-131 Stuff"

Betsy,

As best I can recollect, the following is the sequence of events re the inquiry re Tim Conners (sp?).

Sometime last autumn Charles Land informed me that he had responded to a request from the CDC advisory committee for info on NCI radiation studies and that he had not included our fallout study. I don't recall whether he had included the Utah study, but I don't think so. As I recall, at some point he suggested that I might want to send a followup letter re the fallout study. In the midst of everything else, I, unfortunately, neglected to do this - perhaps in part because both Owen Hoffman (who worked with us on the fallout report, knows its technical content and background very well, and is identified in the report as a participent) and Lynn Lyon were/are on the committee and were/are well aware of both of the studies. (Dr. Lyon was the original P.I. on the Utah study, but for a variety of reasons was replaced by the Dean, Dr. Stevens. Nancy Coleman, the NCI contract officer, or Dr. Stevens can vouch for the reasons.)

It was February (I think) when Dr. Jim Smith, Chief of CDC's
Radation Studies Branch (and the Branch that is carrying out the epidemiology and dose reconstruction studies around the DOE weapons facilities, and the primary user and beneficiary of the advisory committee) called to tell me that Dr./Mr. Conners and one or two other committee members were irritated that I had not sent them information re the fallout study, and that they were considering a letter to very high levels. He suggested that a brief letter to him identifying the study (and other related studies), together with its status and release date would be helpful. I replied to him by letter dated March 10, 1997, a copy of which you and others have. Dr. Smith subsequently complimented me on the letter on several occations, the most recent being early July.

I have not had the time to search through stacks of material, so my next comment has to be qualified, but I do not recall having received or sent direct correspondence to Dr./Mr. Conners, nor do I recall receiving a request for information from the OD office. I do recall Dr. Land showing me a copy of his response, but when he recently asked if a could provide him with a copy, I was unable to do so.

Paul Sloca, the AP reporter from South Dakota, in his initial conversation wtih me made reference to members of the CDC advisory committee and raised points re details in the report that could only have been brought to his attention by someone familiar with the report.

The above is my recollection. I will start looking through things to see if any of the above either a) is in error, or b) can be supplemented.

(You may recall that in early 1996, Owen Hoffman requested information from us that he might use in carrying dose reconstruction studies in the Oak Ridge, TN vicinity. (In recent years he left Oak Ridge National Laboratory to become a consultant for such studies.) Andre Bouville responded to him on February 23, 1996 with considerable information pertaining to the counties in Tennessee.)

ATTACHMENT

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MEMORANDUM

TO: Rich Tarplin,
Dept. of Health and Human Services

FROM: Cybele Bjorklund,
Office of Sen. Tom Daschle

DATE: April 14, 1997

RE: Iodine 131 inquiry

Request: Ann Mills suggested I summarize for you our efforts to obtain information from NCI on the health effects of iodine 131 fallout from the Nevada test site. This information originated from PL 97-114, a 1983 statute requiring the Secretary to conduct research and analyses on thyroid cancer risk and exposure to iodine 131 and nuclear bomb fallout, including fallout from the Nevada tests. We are told that NCI has compiled considerable data and conducted analyses on this matter. Therefore, Sen. Daschle would like answers to the following questions:

- What data have been compiled on the health effects of iodine 131 fallout from NV test sites?
- What analyses and/or conclusions have been reached on that data?
- Has any report on that data has been drafted?
- If so, is it possible to get the latest draft of the report?
- Why hasn't the technical component (which we understand to be complete) of the report been released?
- Why has the NCI failed to release adequate data to scientists involved in dose reconstruction studies in Hanford, WA and Oak Ridge, TN?
- Why was a former Atomic Energy Commission official put in charge of overseeing a project that may be critical of the Atomic Energy Commission?

Status of Inquiry: We were first contacted about this issue in late February, which is when I began talking to NCI. Dr. Bruce Wachholz (NCI) and I exchanged several messages without speaking to each other. In the meantime, Betsy Duane got involved and became my main NCI contact. She and I have spoken a number of times, and she has been quite helpful. Nevertheless, we have been unable to obtain satisfactory answers regarding the Secretary's efforts to respond to PL 97-114, and Sen. Daschle, mindful of his 12-year battle to review government data relating to Agent Orange exposure, has given us direct orders to "leave no stone unturned" in getting to the bottom of this mystery.

Betsy indicated that a short report, as required by PL 97-114, was sent to Congress in a timely manner. However, she was only able to find a pre-clearance draft and did not send that document to me. She confirmed that a comprehensive 1,200 page report is "in clearance" now. She says it is primarily a "user" guide for the data, containing formulas that researchers and others can use to calculate county exposure figures. Betsy maintains there are no conclusions or summary statements in the report. While Sen. Daschle was not involved in the initial legislation, he is concerned that this may not fulfill the spirit of the law.

The charge has been made by members of the scientific community that Dr. Wachholz is "sitting on the data." We take no position on that charge. However, Sen. Daschle does believe he deserves straight answers to his questions. He would also like immediate clarification of what reports, summaries or analyses of these data have been compiled to date.

Any help you could provide in getting timely answers to these questions would be greatly appreciated.

programs funded in whole or in part by Federal funds, and report such recommendations to the Congress within 180 days after the date of the enactment of this Act.

(d) The Secretary of Health and Human Services, acting through the Inspector General of the Department of Health and Human Services, shall undertake a thorough investigation of— Investigation. 42 USC 1395 note.

(1) the methods available to stem fraud and abuse in the provision of home health services under medicare and medicaid; and

(2) the extent to which such methods are applied in stemming such fraud and abuse.

The Secretary shall report the results of the investigation to the Congress within 12 months after the date of the enactment of this Act. Report to Congress.

(e)(1) The Secretary of Health and Human Services shall develop and carry out demonstration projects commencing no later than January 1, 1984, to test— 42 USC 1395 note.

(A) methods for identifying patients at risk of institutionalization who could be treated more cost-effectively with home health services and other non-institutional health services; and

(B) alternative reimbursement methodologies for home health agencies in order to determine the most cost-effective and efficient way of providing home health services.

(2) Methods for identifying patients at risk of institutionalization to be tested by the Secretary under paragraph (1)(A) may include, but not be limited to, the identification of hospitalized medicare patients who are candidates for early discharge due to availability of home health services and individuals in the community who could avoid institutionalization with the availability of home health services.

(3) Reimbursement methodologies to be tested by the Secretary under paragraph (1)(B) may include but not be limited to fee schedules, prospective reimbursement, and capitation payments.

(4) The Secretary shall report to Congress his findings with regard to the demonstrations carried out under paragraph (1) no later than January 1, 1986. Report to Congress.

(f) For purposes of this section, the term "home health services" has the meaning prescribed for the term by section 1861(m) of the Social Security Act. "Home health services." 42 USC 1395 note. 42 USC 1395x.

ANALYSIS OF THYROID CANCERS; ACTIONS BY SECRETARY

SEC. 7. (a) In carrying out section 301 of the Public Health Service Act, the Secretary of Health and Human Services shall— 42 USC 241 note. 42 USC 241.

(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

Report to Congress.

(4) prepare and transmit to the Congress within one year after the date of enactment of this Act a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

ATTACHMENT

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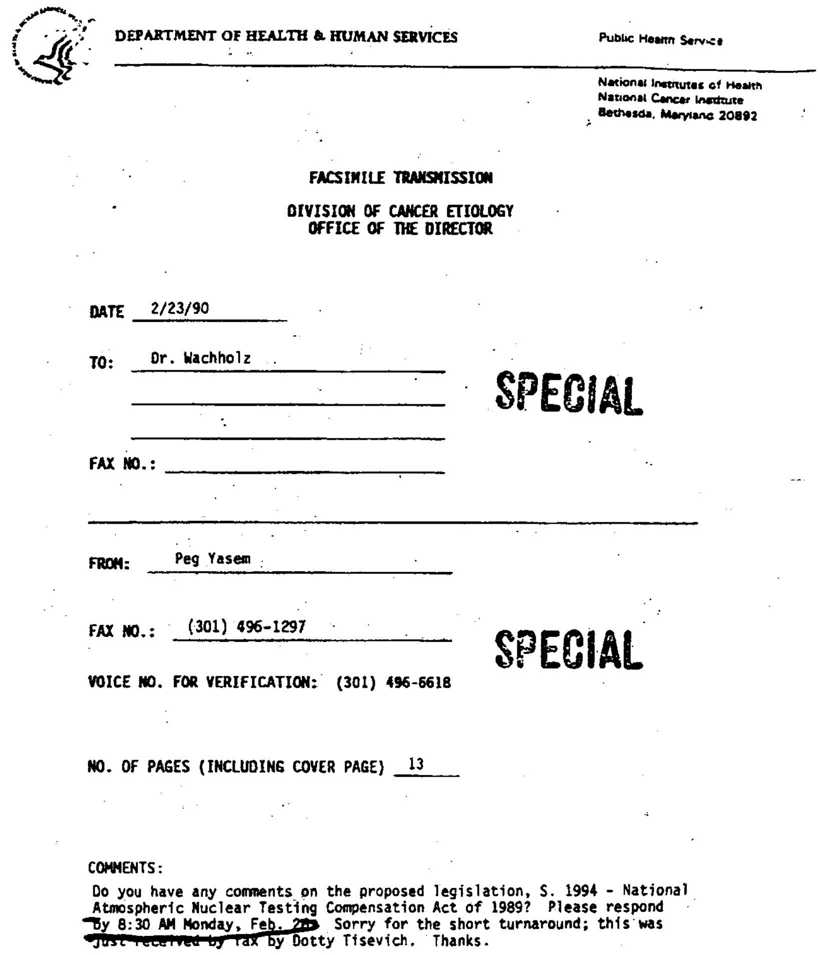


DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

FACSIMILE TRANSMISSION

DIVISION OF CANCER ETIOLOGY
OFFICE OF THE DIRECTOR

DATE 2/23/90

TO: Dr. Wachholz

SPECIAL

FAX NO.:

FROM: Peg Yasem

FAX NO.: (301) 496-1297

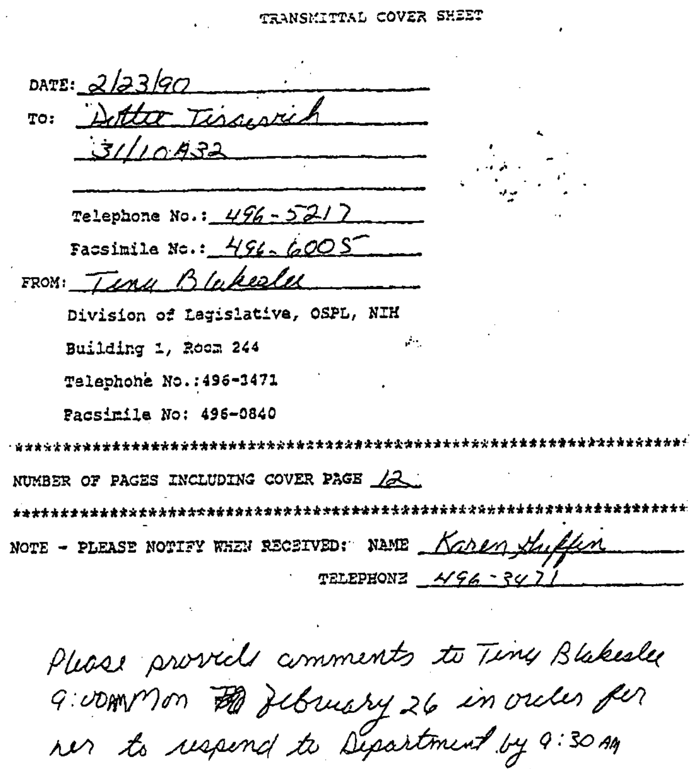
SPECIAL

VOICE NO. FOR VERIFICATION: (301) 496-6618

NO. OF PAGES (INCLUDING COVER PAGE) 13

COMMENTS:

Do you have any comments on the proposed legislation, S. 1994 - National Atmospheric Nuclear Testing Compensation Act of 1989? Please respond by 8:30 AM Monday, Feb. 2[illegible] Sorry for the short turnaround; this was just received by fax by Dotty Tisevich. Thanks.



TRANSMITTAL COVER SHEET

DATE: 2/23/90

TO: Dottie Tisevich

31/10A32

Telephone No.: 496-5217

Facsimile No.: 496-6005

FROM: Tiny Blakeslee

Division of Legislative, OSPL, NIH

Building 1, Room 244

Telephone No.: 496-3471

Facsimile No: 496-0840

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NUMBER OF PAGES INCLUDING COVER PAGE 12

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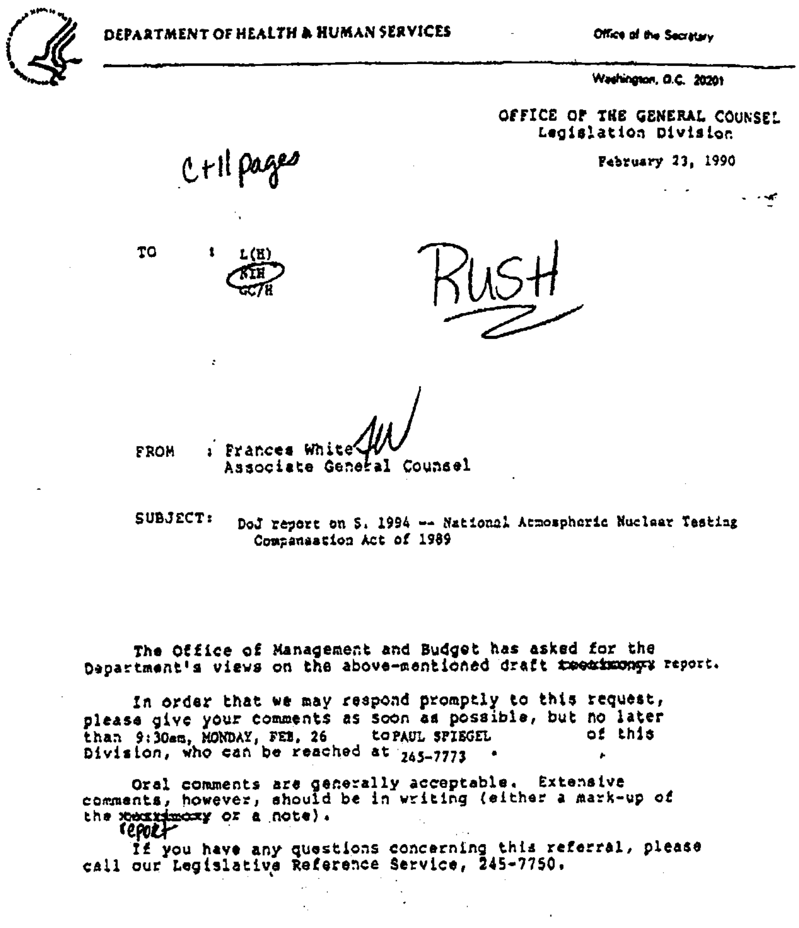
NOTE - PLEASE NOTIFY WHEN RECEIVED: NAME Karen Huffin

TELEPHONE 496-3471

Please provide comments to Tiny Blakeslee 9:00AM Mon February 26 in order for her to respond to Department by 9:30 AM



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

OFFICE OF THE GENERAL COUNSEL
Legislation Division

February 23, 1990

C+11 pages

TO : L(H)
NIH
GC/H

RUSH

FROM : Frances White FW
Associate General Counsel

SUBJECT: DoJ report on S. 1994 -- National Atmospheric Nuclear Testing Compensation Act of 1989

The Office of Management and Budget has asked for the Department's views on the above-mentioned draft ~~testimony~~ report.

In order that we may respond promptly to this request, please give your comments as soon as possible, but no later than 9:30am, MONDAY, FEB. 26 to PAUL SPIEGEL of this Division, who can be reached at 245-7773.

Oral comments are generally acceptable. Extensive comments, however, should be in writing (either a mark-up of the ~~testimony~~ report or a note).

If you have any questions concerning this referral, please call our Legislative Reference Service, 245-7750.

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

Honorable Joseph R. Biden, Jr.
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This proffers the views of the Department of Justice (the "Department") on S. 1994, the "National Atmospheric Nuclear Testing Compensation Act of 1988." For the reasons set forth below, we strongly oppose this legislation.

Modeled on the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10, *et seq.*, S. 1994 proposes across-the-board payments to broad categories of persons without regard to whether the individuals within those categories have (or had) conditions probably and proximately caused by the actions of the United States. The vast majority of persons that would be compensated by S. 1994 were not injured by exposure to radiation. Further, the bill inappropriately provides payments to individuals who already obtained worker compensation remedies. Moreover, the vaccine program in the claims court has been both problematic and expensive. Insofar as S. 1994 relies upon that model, it is encumbered by a structure that is not well suited to the efficient compensation of meritorious claims.

S. 1994 would amend Title XXI of the Public Health Service Act (42 U.S.C. §§ 300aa-1 *et seq.*) to create a new entitlement program to permit certain residents of portions of Utah, Nevada and Arizona to recover up to $50,000 if they contracted specified diseases during the years 1951 through 1958 and 1962. Miners employed in uranium mines located in four states from 1947 to 1971 who contracted lung cancer or other serious respiratory disease could recover up to $100,000 (Section 3). A group of special masters appointed by the Claims Court, which is an Article I court, *see* 28 U.S.C. §171(a), would determine initial adjudications on petitions for compensation. The bill does not require that causation be demonstrated between exposure to radiation and any subsequently developed malady, or that any legal theory of liability on the part of the United States be satisfied through evidentiary proof.

S. 1994 would impose an "arbitrary and capricious" standard for review of special master decisions by Claims Court judges. This restrictive standard of review could present constitutional

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difficulties by vesting significant decisional authority in a new class of officials who are neither Article I judges, Article III judges, nor Executive Branch officers subject to the direction of the President. Although the bill would permit Article I and, eventually, Article III judges, to review the decisions rendered by the special masters, their review would be sharply circumscribed by the arbitrary and capricious standard, and it is unclear that this restricted review power would meet constitutional requirements.

The bill also raises the related issue of vesting, in proposed subsection §142(c), of appointment and for-cause removal authority over the special masters in the Claims Court. The restrictive standard of review for special masters' determinations provided in the bill would, in our view, invest the special masters with "significant authority pursuant to the laws of the United States," *Buckley* v. *Valeo*, 424 U.S. 1, 126 (1976), and accordingly require that their appointment and removal be consistent with constitutional provisions governing "officers of the United States." The Appointments Clause of the Constitution, Art. II, sec. 2, cl. 2, vests Congress with the authority to provide for the appointment of inferior officers of the United States by "the President alone, . . . the Courts of Law, or . . . the Heads of Departments." There is a substantial question whether the Claims Court, an Article I tribunal, is a "Court[] of Law" within the meaning of the Appointments Clause. *Cf. Pacemaker Diagnostic Clinic of America, Inc.* v. *Intromedix, Inc.*, 725 F.2d 537, 544-45 (9th Cir.) (en banc) (upholding constitutionality of congressional designation of Article III judges to select and appoint magistrates under the Federal Magistrate Act), *cert. denied*, 469 U.S. 824 (1984). Accordingly, we doubt whether, consistent with the Appointments Clause, the Claims Court may be invested with power to appoint and remove such officers, or that such officers may be insulated from removal by a for-cause removal requirement.

In addition to these constitutional defects, the bill is fundamentally flawed by its very premise: that a special remedy permitting a preferred class of claimants to avoid the provisions of the Federal Tort Claims Act ("FTCA") should be enacted when available scientific evidence does not support the conclusion that many cancers have been caused through the government's Atmospheric Atomic Testing Program or its activities with regard to uranium miners.

Subject to carefully defined exceptions and exclusions, the Federal Tort Claims Act provides a complete and comprehensive damage remedy for personal injury or wrongful death claims caused by the negligence or wrongful conduct of government personnel. S. 1994 completely disregards this generally applicable remedy

and enacts a regime of absolute liability without requiring proof of either causation in fact or proximate to the injury alleged.

Under the FTCA, "liability does not arise by virtue either of United States ownership of an inherently dangerous commodity or property, or by engaging in an 'extra hazardous activity'." Dalehite v. United States, 346 U.S. 15, 45 (1953). In recognition of the unique governmental nature of certain activities and decisions, matters which are discretionary functions may not form a basis of liability. 28 U.S.C. § 2680(a).

Because persons outside the subject class who have claims against the United States similar to those within the class may pursue them under traditional theories and by traditional vehicles, we see no demonstrable reason to provide for an alternate, automatic remedy more favorable to putative class-member plaintiffs than that provided in all other litigation under the Federal Tort Claims Act.

The types of claims asserted in lawsuits against the United States under the Federal Tort Claims Act are as broad as the reach of the federal government's activities and operations. The exemptions and exclusions to that Act express the congressional recognition that there must be reasonable limits to the taxpayers' burden of paying to pay claims. Especially in view of the less-than-compelling evidence to support change, we believe that the traditional FTCA regime (and, where applicable, workers' compensation) should apply to the subjects of S. 1994 as they do for any other tort claims that could be maintained against the United States.

There is no current justification for the disparate treatment of legally and factually similar claims. This is especially the case because the illnesses covered by the bill are relatively common, and the evidence of harm caused by low-level exposure to radiation falls far short of demonstrating that significant numbers of uncompensated injuries have occurred.

National Cancer Institute data illustrate that approximately
~~National Cancer Institute data illustrate that approximately~~ 985,000 people in the United States will be diagnosed as having cancer this year. If skin cancer is also considered, the cancer diagnoses anticipated this year increase to nearly one and one-half million.[1] "About 75 million Americans now living will

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[1] American Cancer Society: 1988 CANCER FACTS & FIGURES, American Cancer Society at 3. These estimates are based upon incidence rates from the National Cancer Institute SEER Program (1983-1984).

eventually have cancer: about 30%, according to present rates. Over the years, cancer will strike in approximately three out of four families."[2]

Although ionizing radiation is the most extensively studied human carcinogen,[3] it is less significant as a cause of cancer when viewed in comparison with other carcinogens. In fact, the National Institutes of Health have determined that "[l]ess than 3% of the U.S. cancer burden can be . . . attributed to ionizing radiation from natural sources and human activities, compared to around 30% for tobacco smoking."[4] Of the ionizing radiation from natural sources and human activities, about 1.5% is attributable to atmospheric weapons tests (current testing by countries such as India, China and France which are not test-ban treaty signatories), and continuing fallout from the testing which occurred in the 1950s and 1960s.[5]

Our most-definitive information about the health effects of radiation is derived from the Japanese atomic bomb survivors. As the National Institute of Health has noted, among 6,035 atom bomb survivors who were exposed to high levels of radiation, there were 498 cancer deaths from 1950 to 1978, when only 323 deaths would be expected, a differential of 54 per cent.[6] But, among

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[2] Id.

[3] D. SCHOTTENFELD and J. FRAUMENI, CANCER EPIDEMIOLOGY AND PREVENTION (1982), at 231.

[4] NIH: "Report of the National Institutes of Health Ad Hoc Working Group to develop Radioepidemiological Tables," p. 13 (citing S. JABLON and J. BAILAR, "The Contribution of Ionizing Radiation to Cancer Mortality in the United States." Preventive Medicine 9:219-222 (1980).

[5] National Research Council: "The Effect on Populations of Exposure to Low Levels of Ionizing Radiation: 1980 (BEIR III), at 99.

[6] NIH, supra, at p. 13 (citing H. KATO and W.J. SCHULL, "Studies of the Mortality of A-Bomb Survivors." Radiation Research 90:395-432 (1982)).

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survivors who were exposed to low-level radiation, fewer cancer deaths than would normally be expected were observed.[7]

S. 1994, as it pertains to the so-called "downwind residents," is based upon the fundamental, but insupportable, premise that:

> fallout emitted during the Government's above-ground nuclear tests in Nevada exposed civilians who lived in the downwind affected area in Nevada, Utah, and Arizona to radiation that generated an excess of cancers among these civilians.[8]

The most recent National Cancer Institute data published in the American Journal of Epidemiology plainly show that the sponsors' premise is erroneous.[9] On the contrary, the National Cancer Institute researchers found a significantly lower cancer incidence in the relevant geographical area:

> Even after correction for difference in baseline cancer risk between Mormon and non-Mormons, cancer mortality during 1964-1980, i.e., 11-27 years[10] after the heaviest fallout deposition in 1953, was significantly lower in southwestern Utah (the area nearest

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[7] Id.

[8] Section 2(1).

[9] S.G. Machado, C.E. Land, and F.W. McKay, "Cancer Mortality and Radioactive Fallout in Southwestern Utah," American Journal of Epidemiology, Vol. 125, No. 1, p. 44.

[10] The generally accepted minimum latency period (the time period between radiation exposure and disease diagnosis) for cancers other than leukemia is 5 to 10 years. Cancers diagnosed during this period between exposure and diagnosis are assumed to be unrelated to the radiation exposure. Thus, the National Cancer Institute study appropriately considered only cases which were diagnosed 11 to 27 years after exposure.

> the Nevada Test Site), than in the rest of the state.[11]

This finding is consistent with earlier studies which demonstrated that the incidence of thyroid cancer among children living near the test site was less than the incidence among children minimally exposed to radiation from the test site. According to the National Academy of Science BEIR III Report:

> Two groups of children -- one group of 2,691 residing in a relatively high fallout area of Utah and Nevada, and another group of 2,140 in a minimal fallout area of Arizona during their infancy and early childhood -- were compared by Rallison and co-workers for evidence of thyroid disease. Benign neoplasms were observed in 6 exposed and 10 nonexposed children. Two carcinomas were found, but only in the nonexposed children, 15-20 years after the fallout period.[12]

An increase in leukemia among residents in the Utah counties nearest the test site has been detected. However, the association of this increase with fallout exposure is suspect because there was a coexistent increase noted in a type of leukemia unrelated to radiation exposure. Moreover, there was a similar increased leukemia incidence which occurred even prior to the use of the Nevada Test Site. Accordingly, the NIH experts concluded that "(t)hese observations suggest the possibility of a generally elevated leukemia risk in southwestern Utah, unrelated to fallout exposure."[13]

An increase in childhood leukemia also was detected, but the researchers noted "that there were only 12 childhood deaths from leukemia in southwestern Utah during 1950-1969," which they regarded as "unremarkable in terms of rates for Utah as a whole." The experts also gave a number of reasons for cautioning against the assumption that the increase was attributable to radiation exposure.[14] Thus, the most current data do not support the notion that an "epidemic" occurred; indeed, with the possible exception of childhood leukemia, the data show that there was a substantial decrease in cancer incidence.

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[11] Id., at 37.

[12] "The Effects on Population of Exposure to Low Levels of Ionizing Radiation: 1980" (BEIR III), National Academy Press, p. 300. This study is now being updated by the original investigators at the University of Utah.

[13] Machado, et al., at 55.

Furthermore, downwinders compensation under S. 1994 would depend upon only three criteria: (1) the claimant lived in certain counties of Utah, Nevada, or Arizona, (2) during particular time periods, and (3) contracted a specific disease. These general criteria would allow the compensation of persons whose diseases are probably unrelated in any way (setting aside even a proximate causation standard) to any asserted radiation exposures. For example, the criteria expressly would permit payment of compensation to persons who have contracted multiple myeloma. According to the National Institutes of Health study, which was mandated by Congress under Section 7(b) of the Orphan Drug Act of January 4, 1983 (Pub.L. No. 97-414), the relationship between multiple myeloma and radiation exposure is described as "uncertain" and doubtful.[15]

The criteria also would allow compensation of persons who contracted lung, female breast, stomach, colon, esophageal, and urinary tract cancer, regardless of the radiation dose they received. The NIH study, which was intended by Congress to quantify the association of cancer with radiation doses, plainly demonstrated that these cancers are probably unrelated to the low doses received by persons who lived in the test site vicinity.[16] Even assuming the exaggerated doses calculated by plaintiff's consultant in the Allen litigation,[17] a causal relationship between these diseases and the plaintiffs' asserted doses is improbable according to the NIH study.[18] This is the very study mandated by Congress to examine the exact issues raised by S. 1994.

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[14] Id., at 55.

[15] Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables, National Institutes of Health (1985), p. 282.

[16] See references cited in American Journal of Epidemiology, supra, at 46. See Also, L.R. Anspaugh and B. W. Church, "Historical Estimates of External Gamma Exposure and Collective External Gamma Exposure from Testing at the Nevada Test Site," Health Physics, Vol. 51, No. 1, p. 35.

[17] The doses calculated by plaintiffs' expert witness, John Gofman, and by the other experts are noted in Allen v. United States, 588 F. Supp. 247, 428 (1984).

The criteria also take no account of more plausible proximate causes of diseases such as lung and colon cancer. Thus, a heavy smoker, predisposed to lung cancer, and a person with a high fat-low fiber diet, predisposed to colon cancer, could the same payments as any other member of the group defined by the bill, irrespective of the improbable proximate relationship between their radiation doses and the particular diseases that they have contracted.

The criteria also are deficient in permitting no analysis of a claimant's latency period -- the time period between radiation exposure and diseases diagnoses. Such an analysis is typically useful because cancers, characterized by latency periods which are significantly shorter or longer than observed minimum or maximum latency periods, are probably not related to radiation exposure and should be excluded based upon reliable scientific data. In fact, on the basis of numerous epidemiological studies, the NIH study concluded that cancers (other than leukemia and bone cancer) with latency periods less than five years were not caused by radiation exposure.[19] This regime stands in contrast to that contained in the National Vaccine Injury Compensation Program which sets out a time period between vaccine administration on the onset of the first symptom or manifestation of the disease.

In summary, S. 1994 would permit compensation for cancers whose causal relationship to radiation is dubious. The bill's criteria would allow awards where the doses are probably too low to cause most of the cancers specified as compensable, according to the congressionally-mandated NIH report. The criteria take no account of more plausible cancer-causing agents, such as tobacco. They permit no analysis of latency periods, which would reliably isolate cancers unrelated to radiation exposures.

Under S. 1994, a petitioner would be entitled to compensation upon a finding "on the record as a whole that the petitioner has shown the matters required under subsection 2142(a)(1)." There is no standard of proof set forth in the bill

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[18] Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables, at pp. 126 et seq.

[19] Id., at 59.

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and nor any requirement for a affirmative finding of causation. Even the National Childhood Vaccine Injury Compensation Program requires these findings to support compensation awards.

The apparent rationale for providing special compensation to miners, rather than workers in all strategic industries who have suffered occupational illnesses, is that the miners labored in private mines which "were providing uranium for the sole use and benefit of the nuclear weapons program of the United States Government . . . ."[20] (Emphasis supplied.) The bill, however, would compensate miners who worked in all of the uranium mines in Colorado, New Mexico, Arizona, and Utah between 1947 and 1971, when only a portion of the uranium mined in these states during that time period was used in the nuclear weapons program. Further, each state's worker compensation scheme makes compensation available for miners' injuries on the job including radiation related injuries. In short, the miners already have a remedy available to them.

The bill's criteria for compensating the uranium miners, like the criteria for compensating those allegedly exposed to fallout, contain no provision for analyzing latency periods. Thus, a miner with a lung cancer latency period of one year would be paid, despite the clear scientific consensus that so short a time between exposure and diagnosis is incompatible with a finding that the cancer was caused by radiation.[21]

S. 1994 also would compensate miners who have contracted "other serious respiratory disease(s)."[22] The National Academy of Science BEIR IV Committee review of the epidemiological studies which have considered nonmalignant respiratory diseases among miners reveals that the studies are inconsistent in their findings, plagued by insufficient data, and do not assess the effects of other harmful agents to which miners are exposed.[23]

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[20] Section 2(3).

[21] Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables, at. p. 89.

[22] Subsection 2142(c)(1)(A)(ii)(III).

[23] "Health Risks of Radon and Other Internally Deposited Alpha-Emitters" (BEIR IV), National Academy Press (1988), pp. 489-90.

In short, we are strongly opposed to S. 1994 in its current form because it would establish a broad, unjustified, and expansive entitlement program based upon a Claims Court model that has suffered from significant practical problems. Moreover, the decision-making structure of S. 1994 raises serious constitutional questions. We appreciate your consideration of our views.

The Office of Management and Budget has advised that there is no objection to the presentation of this report and that enactment of S. 1944 would not be in accord with the program of the President.

Sincerely,

Bruce C. Navarro
Acting Assistant Attorney General

⑪

Two studies (Machado + the \$7×10^6 study) have found more leukemias in SW Utah, ie, Washington county, presumably among those who were there in 1953, than would be expected on the basis of all-Utah rates. The excess among children is the more striking, & the hardest to argue against.

Moreover, according to BEIR V, an excess would be expected. On pg 168, the following risks are estimated:

For exposures before age 20, RR within 15 yrs after exposure to dose D in Gy is

$$1 + .243 \times D \times \exp(4.885) = 1 + 32.15 \times D \;;$$

RR for 15-25 years after exposure is

$$1 + .243 \times D \times \exp(2.380) = 1 + 2.626 \times D \,.$$

(RR is 1.0 afterwards)

For exposures ~~after~~ age 20, RR is

$$1 + .243 \times D \times \exp(2.367) = 1 + 2.592 \times D$$

within 25 years, and for 25-30 years afterward,

$$1 + .243 \times D \times \exp(1.638) = 1 + 1.250 \times D$$

& zero thereafter.

In tabular form, ~~[illegible]~~ RR ~~≠~~= (PC in parentheses)

		Dose			
age at exp	time period	.5 cGy	1 cGy	2 cGy	3 cGy
<20	<15	1.161 (.14)	1.3215 (.24)	1.643 (.39)	1.965 (.49)
<20	15-25	1.013 (.013)	1.026 (.025)	1.052 (.049)	1.078 (.072)
>20	<25	1.013 (.013)	1.026 (.025)	1.052 (.049)	1.078 (.072)
>20	25-30	1.006 (.006)	1.0125 (.012)	1.025 (.024)	1.0375 (.036)

~~If a childhood case had > 3 cGy, the PC would be~~

On the basis of BEIR II, then, some childhood ~~cancer~~ leukemia case in Wash county would get compensated under Tort law, + ~~as~~ if the PC tables logic were followed (I think some compensation was originally intended for a pc over 10%.), perhaps every childhood leukemia in Utah would qualify, ~~(?)~~ provided the child was born before 1957 or so.

~~On the other hand nobody else would qualify — i.e., no adult ca. case (except, according to BEIR V, someone exposed at age 19 who died at age 34)~~

~~except those~~

also, as long as death occurred within 15 yrs, leukemias among persons ~~of~~ who were under 20 at some time before 1957 (?)

But nobody else — and nobody with another cancer.

wgt: science
childhood exposure > 1 rad ... } compensation
c̄ leukemia w/in 15 yrs

no other ages / cancers

be aware of BEIR I
ground cut out under them

~~[illegible]~~ : BEIR I
Utah Study

omit ref to multiple myeloma
"pushing it"

lottery - [illegible] !

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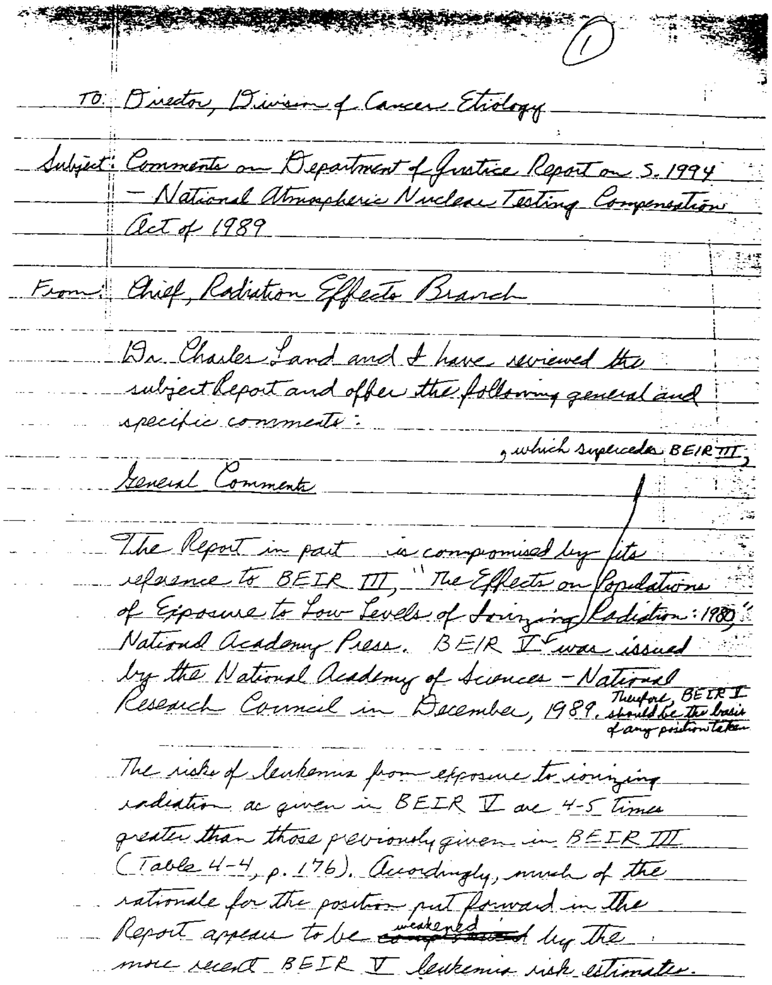
geography tied to [illegible] ?

childhood exp c̄ [illegible] w/in 15 yrs - OK
[illegible]



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TO: Director, Division of Cancer Etiology

Subject: Comments on Department of Justice Report on S. 1994 – National Atmospheric Nuclear Testing Compensation Act of 1989

From: Chief, Radiation Effects Branch

Dr. Charles Land and I have reviewed the subject Report and offer the following general and specific comments:

General Comments

The Report in part is compromised by its reference to BEIR III, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980," National Academy Press. BEIR V, which supercedes BEIR III, was issued by the National Academy of Sciences – National Research Council in December, 1989. Therefore, BEIR V should be the basis of any position taken.

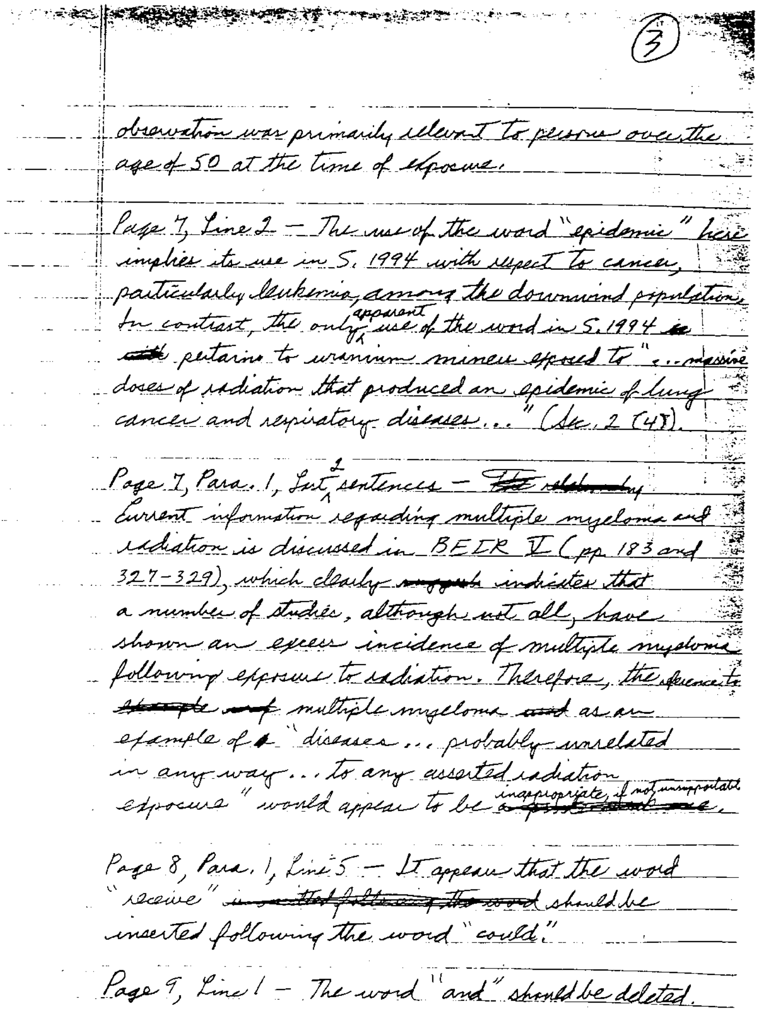
The risks of leukemia from exposure to ionizing radiation as given in BEIR V are 4-5 times greater than those previously given in BEIR III (Table 4-4, p. 176). Accordingly, much of the rationale for the position put forward in the Report appears to be ~~compromised~~ weakened by the more recent BEIR V leukemia risk estimates.

In fact, the attached table illustrates the relative risk values (and the associated probability of causation estimates) derived from BEIR V (p. 168) as a function of the age at exposure, latency, and dose. From this it can be ~~[illegible]~~ seen that persons exposed before the age of 20 and who developed leukemia within 15 years following exposure were at greatest risk. According to this table, even under Tort Law apparently any child (<20 yrs) who ~~[illegible]~~ received a dose > 30 mGy (3 rad) would be compensated, and if compensation were based upon the probability of causation, e.g., 10%, every child receiving a dose of 5 mGy (500 mrad) would receive some compensation.

The association of leukemia in Southwestern Utah with fallout has been studied by both Machado, et. al. and ~~study, and the current study being carried out~~ the University of Utah (whose report is not yet complete and therefore unavailable and unreferencable). Both studies found an excess of leukemia among children present at the time (as acknowledged in the last paragraph on page 6 of the Report), an excess that would be expected according to BEIR V.

Specific Comments

Page 6, Para. 2, Last sentence – This is correct, but the statement does not ~~[illegible]~~ indicate that the



③

observation was primarily relevant to persons over the age of 50 at the time of exposure.

Page 7, Line 2 – The use of the word "epidemic" here implies its use in S. 1994 with respect to cancer, particularly leukemia, among the downwind population. In contrast, the only apparent use of the word in S. 1994 ~~is~~ ~~it~~ pertains to uranium miners exposed to "...massive doses of radiation that produced an epidemic of lung cancer and respiratory diseases..." (Sec. 2 (4)).

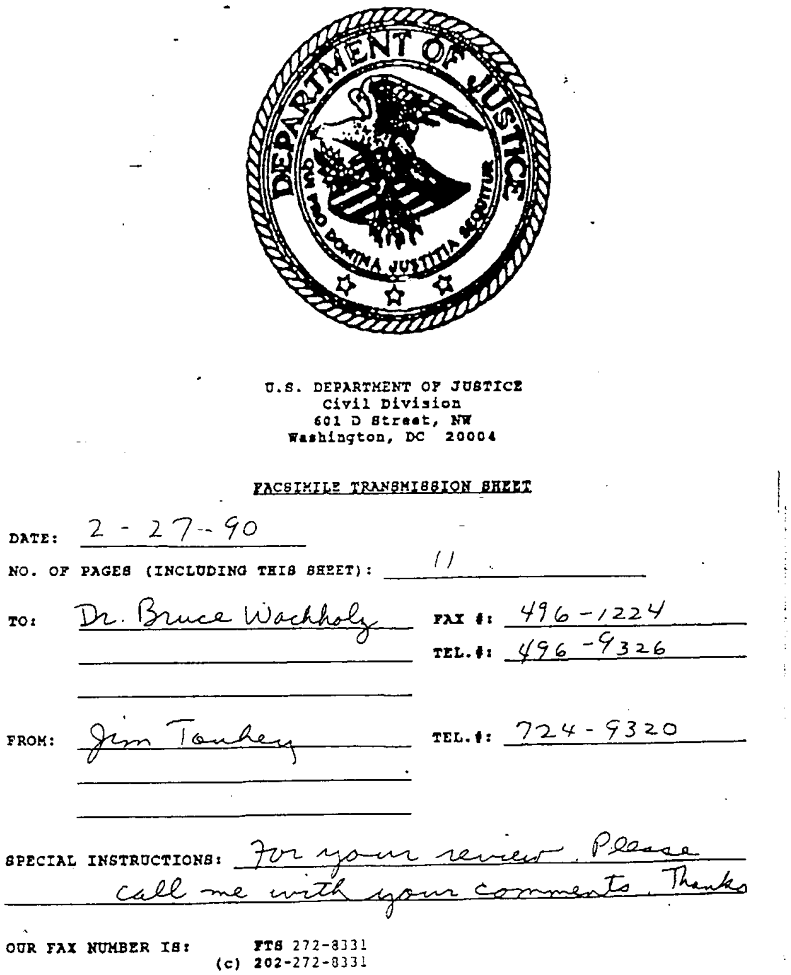
Page 7, Para. 1, Last 2 sentences – ~~The~~ ~~[illegible]~~ Current information regarding multiple myeloma and radiation is discussed in BEIR V (pp. 183 and 327-329), which clearly ~~suggests~~ indicates that a number of studies, although not all, have shown an excess incidence of multiple myeloma following exposure to radiation. Therefore, the reference to ~~example~~ ~~of~~ multiple myeloma ~~and~~ as an example of ~~a~~ "diseases... probably unrelated in any way... to any asserted radiation exposure" would appear to be inappropriate, if not unsupportable ~~a [illegible]~~.

Page 8, Para. 1, Line 5 – It appears that the word "receive" ~~is omitted following the word~~ should be inserted following the word "could."

Page 9, Line 1 – The word "and" should be deleted.

		DOSE							
		5 mGy (500 mrad)		10 mGy (1 rad)		20 mGy (2 rad)		30 mGy (3 rad)	
Age at Exposure (yrs)	Latent Period (yrs)	RR[a]	PC[b]	RR	PC	RR	PC	RR	PC
< 20	< 15	1.161	0.14	1.322	0.24	1.643	0.39	1.965	0.49
< 20	15-25	1.013	0.013	1.026	0.025	1.052	0.049	1.078	0.072
> 20	< 25	1.013	0.013	1.026	0.025	1.052	0.049	1.078	0.072
> 20	25-30	1.006	0.06	1.013	0.012	1.025	0.024	1.038	0.036

a: Relative Risk
b: Probability of Causation



U.S. DEPARTMENT OF JUSTICE
Civil Division
601 D Street, NW
Washington, DC 20004

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TO: Dr. Bruce Wachholz

FAX #: 496-1224

TEL.#: 496-9326

FROM: Jim Touhey

TEL.#: 724-9320

SPECIAL INSTRUCTIONS: For your review. Please call me with your comments. Thanks

OUR FAX NUMBER IS: FTS 272-8331
(c) 202-272-8331

U. S. Department of Justice

Washington, DC 20530

Honorable Joseph R. Biden, Jr.
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This proffers the views of the Department of Justice (the "Department") on S. 1994, the "National Atmospheric Nuclear Testing Compensation Act of 1989." For the reasons set forth below, we strongly oppose this legislation.

Modeled on the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10, et seq., S. 1994 proposes across-the-board payments to broad categories of persons without regard to whether the individuals within those categories have (or had) conditions probably and proximately caused by the actions of the United States. The vast majority of persons that would be compensated by S. 1994 were not injured by exposure to radiation. Further, the bill inappropriately provides payments to individuals who already obtained worker compensation remedies. Moreover, the Vaccine Program in the Claims Court has been both problematic and expensive. Insofar as S. 1994 relies upon that model, it is encumbered by a structure that is not well suited to the efficient compensation of meritorious claims.

S. 1994 would amend Title XXI of the Public Health Service Act (42 U.S.C. §§ 300aa-1 et seq.) to create a new entitlement program to permit certain residents of portions of Utah, Nevada and Arizona to recover up to $50,000 if they contracted specified diseases during the years 1951 through 1958 and 1962. Miners employed in uranium mines located in four states from 1947 to 1971 who contracted lung cancer or other serious respiratory disease could recover up to $100,000 (Section 3). A group of special masters appointed by the Claims Court, which is an Article I court, see 28 U.S.C. §171(a), would determine initial adjudications on petitions for compensation. The bill does not require that causation be demonstrated between exposure to radiation and any subsequently developed malady, or that any legal theory of liability on the part of the United States be satisfied through evidentiary proof.

S. 1994 would impose an "arbitrary and capricious" standard for review of special master decisions by Claims Court judges. This restrictive standard of review could present constitutional

difficulties by vesting significant decisional authority in a new class of officials who are neither Article I judges, Article III judges, nor Executive Branch officers subject to the direction of the President. Although the bill would permit Article I and, eventually, Article III judges, to review the decisions rendered by the special masters, their review would be sharply circumscribed by the arbitrary and capricious standard, and it is unclear that this restricted review power would meet constitutional requirements.

The bill also raises the related issue of vesting, in proposed subsection 2143(c), of appointment and for-cause removal authority over the special masters in the Claims Court. The restrictive standard of review for special masters' determinations provided in the bill would, in our view, invest the special masters with "significant authority pursuant to the laws of the United States," Buckley v. Valeo, 424 U.S. 1, 126 (1976), and accordingly require that their appointment and removal be consistent with constitutional provisions governing "Officers of the United States." The Appointments Clause of the Constitution, Art. II, sec. 2, cl. 2, vests Congress with the authority to provide for the appointment of inferior officers of the United States by "the President alone, . . . the Courts of Law, or . . . the Heads of Departments." There is a substantial question whether the Claims Court, an Article I tribunal, is a "Court[] of Law" within the meaning of the Appointments Clause. Cf. Pacemaker Diagnostic Clinic of America, Inc. v. Intromedix, Inc., 725 F.2d 537, 544-45 (9th Cir.) (en banc) (upholding constitutionality of congressional designation of Article III judges to select and appoint magistrates under the Federal Magistrate Act), cert. denied, 469 U.S. 824 (1984). Accordingly, we doubt whether, consistent with the Appointments Clause, the Claims Court may be invested with power to appoint and remove such officers, or that such officers may be insulated from removal by a for-cause removal requirement.

In addition to these constitutional defects, the bill is fundamentally flawed by its very premise: that a special remedy permitting a preferred class of claimants to avoid the provisions of the Federal Tort Claims Act ("FTCA") should be enacted when available scientific evidence does not support the conclusion that many cancers have been caused through the government's Atmospheric Atomic Testing Program or its activities with regard to uranium miners.

Subject to carefully defined exceptions and exclusions, the Federal Tort Claims Act provides a complete and comprehensive damage remedy for personal injury or wrongful death claims caused by the negligence or wrongful conduct of government personnel. S. 1994 completely disregards this generally applicable remedy

and enacts a regime of absolute liability without requiring proof of either causation in fact or proximate to the injury alleged.

Under the FTCA, "liability does not arise by virtue either of United States ownership of an inherently dangerous commodity or property, or by engaging in an 'extra hazardous activity'." Dalehite v. United States, 346 U.S. 15, 45 (1953). In recognition of the unique governmental nature of certain activities and decisions, matters which are discretionary functions may not form a basis of liability. 28 U.S.C. § 2680(a).

Because persons outside the subject class who have claims against the United States similar to those within the class may pursue them under traditional theories and by traditional vehicles, we see no demonstrable reason to provide for an alternate, automatic remedy more favorable to putative class-member plaintiffs than that provided in all other litigation under the Federal Tort Claims Act.

The types of claims asserted in lawsuits against the United States under the Federal Tort Claims Act are as broad as the reach of the federal government's activities and operations. The exemptions and exclusions to that Act express the congressional recognition that there must be reasonable limits to the taxpayers' burden of paying to pay claims. Especially in view of the less-than-compelling evidence to support change, we believe that the traditional FTCA regime (and, where applicable, workers' compensation) should apply to the subjects of S. 1994 as they do for any other tort claims that could be maintained against the United States.

There is no current justification for the disparate treatment of legally and factually similar claims. This is especially the case because the illnesses covered by the bill are relatively common, and the evidence of harm caused by low-level exposure to radiation falls far short of demonstrating that significant numbers of uncompensated injuries have occurred.

National Cancer Institute data illustrate that approximately 985,000 people in the United States will be diagnosed as having cancer this year. If skin cancer is also considered, the cancer diagnoses anticipated this year increase to nearly one and one-half million.[1] "About 75 million Americans now living will eventually have cancer; about 30%, according to present rates. Over the years, cancer will strike in approximately three out of four families."[2]

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[1] American Cancer Society: 1988 CANCER FACTS & FIGURES, American Cancer Society at 3. These estimates are based upon incidence rates from the National Cancer Institute SEER Program (1982-1984).

Although ionizing radiation is the most extensively studied human carcinogen,[3] it is less significant as a cause of cancer when viewed in comparison with other carcinogens. In fact, the National Institutes of Health have determined that "[l]ess than 3% of the U.S. cancer burden can be . . . attributed to ionizing radiation from natural sources and human activities, compared to around 30% for tobacco smoking."[4] Of the ionizing radiation from natural sources and human activities, less than .03% is attributable to atmospheric weapons tests (current testing by countries such as India, China and France which are not test-ban treaty signatories), and continuing fallout from the testing which occurred in the 1950s and 1960s.[5]

Our most-definitive information about the health effects of radiation is derived from the Japanese atomic bomb survivors. As the National Institute of Health has noted, among 6,035 atom bomb survivors who were exposed to high levels of radiation, there were 498 cancer deaths from 1950 to 1978, when only 323 deaths would be expected, a differential of 54 per cent.[6] But, among survivors who were exposed to low-level radiation, fewer cancer deaths than would normally be expected were observed (although the deficit was not statistically significant).[7]

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[2] Id.

[3] D. SCHOTTENFELD and J. FRAUMENI, CANCER EPIDEMIOLOGY AND PREVENTION (1982), at 231.

[4] NIH: "Report of the National Institutes of Health *Ad Hoc* Working Group to develop Radioepidemiological Tables," p. 13 (citing S. JABLON and J. BAILER, "The Contribution of Ionizing Radiation to Cancer Mortality in the United States." *Preventive Medicine* 9:219-222 (1980).

[5] National Research Council: "The Health Effects Of Exposure To Low Levels Of Ionizing Radiation": 1990 (BEIR V), at 18.

[6] NIH, *supra*, at p. 13 (citing H. KATO and KW. SCHULL, "Studies of the Mortality of A-Bomb Survivors." *Radiation Research* 90:395-432 (1982)).

S. 1994, as it pertains to the so-called "downwind residents," is based upon the fundamental, but insupportable, premise that:

> fallout emitted during the Government's above-ground nuclear tests in Nevada exposed civilians who lived in the downwind affected area in Nevada, Utah, and Arizona to radiation that generated an excess of cancers among these civilians.[8]

The most recent National Cancer Institute data published in the American Journal of Epidemiology plainly show that the sponsors' premise is erroneous.[9] On the contrary, the National Cancer Institute researchers found a significantly lower cancer incidence in the relevant geographical area:

> Even after correction for difference in baseline cancer risk between Mormon and non-Mormons, cancer mortality during 1964-1980, i.e., 11-27 years[10] after the heaviest fallout deposition in 1953, was significantly lower in southwestern Utah (the area nearest

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[7] Id.

[8] Section 2(1).

[9] S.G. Machado, C.E. Land, and F.W. McKay, "Cancer Mortality and Radioactive Fallout in Southwestern Utah," American Journal of Epidemiology, Vol. 125, No. 1, p. 44.

[10] The generally accepted minimum latency period (the time period between radiation exposure and disease diagnosis) for cancers other than leukemia is 5 to 10 years. Cancers diagnosed during this period between exposure and diagnosis are assumed to be unrelated to the radiation exposure. Thus, the National Cancer Institute study appropriately considered only cases which were diagnosed 11 to 27 years after exposure.

the Nevada Test Site), than in the rest of the state.[11]

This finding is consistent with earlier studies which demonstrated that the incidence of thyroid cancer among children living near the test site was less than the incidence among children minimally exposed to radiation from the test site. According to the National Academy of Science BEIR III Report:

> Two groups of children -- one group of 2,691 residing in a relatively high fallout area of Utah and Nevada, and another group of 2,140 in a minimal fallout area of Arizona during their infancy and early childhood -- were compared by Rallison and co-workers for evidence of thyroid disease. Benign neoplasms were observed in 6 exposed and 10 nonexposed children. Two carcinomas were found, but only in the nonexposed children, 15-20 years after the fallout period.[12]

An increase in leukemia among residents in the Utah counties nearest the test site has been detected. However, the association of this increase with fallout exposure is suspect because there was a coexistent increase noted in a type of leukemia unrelated to radiation exposure. Moreover, there was a similar increased leukemia incidence which occurred even prior to the use of the Nevada Test Site. Accordingly, the NIH experts concluded that, for persons over age 50 at the time of diagnosis, "(t)hese observations suggest the possibility of a generally elevated leukemia risk in southwestern Utah, unrelated to fallout exposure."[13]

An increase in childhood leukemia also was detected, but the researchers noted "that there were only 12 childhood deaths from leukemia in southwestern Utah during 1950-1980," which they regarded as "unremarkable in terms of rates for Utah as a whole." The experts also gave a number of reasons for cautioning against the assumption that the increase was attributable to radiation exposure.[14]

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[11] Id., at 53.

[12] "The Effects on Population of Exposure to Low Levels of Ionizing Radiation: 1980" (BEIR III), National Academy Press, p. 300. This study is now being updated by the original investigators at the University of Utah.

[13] Machado, et al., at 55.

Downwinders compensation under S. 1994 would depend upon only three criteria: (1) the claimant lived in certain counties of Utah, Nevada, or Arizona, (2) during particular time periods, and (3) contracted a specific disease. These general criteria would allow the compensation of persons whose diseases are probably unrelated in any way (setting aside even a proximate causation standard) to any asserted radiation exposures.

The criteria also would allow compensation of persons who contracted lung, female breast, stomach, colon, esophageal, and urinary tract cancer, regardless of the radiation dose they received. The NIH study, which was intended by Congress to quantify the association of cancer with radiation doses, plainly demonstrated that these cancers are probably unrelated to the low doses received by persons who lived in the test site vicinity.[15] Even assuming the exaggerated doses calculated by plaintiff's consultant in the Allen litigation,[16] a causal relationship between these diseases and the plaintiffs' asserted doses is improbable according to the NIH study.[17] This is the very study mandated by Congress to examine the exact issues raised by S. 1994.

The criteria also take no account of more plausible proximate causes of diseases such as lung and colon cancer. Thus, a heavy smoker, predisposed to lung cancer, and a person with a high fat-low fiber diet, predisposed to colon cancer, could receive the same payments as any other member of the group defined by the bill, irrespective of the improbable proximate relationship between their radiation doses and the particular diseases that they have contracted.

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[14] Id., at 55.

[15] See references cited in American Journal of Epidemiology, supra, at 46. See also, L.R. Anspaugh and B. W. Church, "Historical Estimates of External Gamma Exposure and Collective External Gamma Exposure from Testing at the Nevada Test Site," Health Physics, Vol. 51, No. 1, p. 35.

[16] The doses calculated by plaintiffs' expert witness, John Gofman, and by the other experts are noted in Allen v. United States, 588 F. Supp. 247, 428 (1984).

[17] Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables, at pp. 126 et seq.

The criteria also are deficient in permitting no analysis of a claimant's latency period -- the time period between radiation exposure and diseases diagnoses. Such an analysis is typically useful because cancers, characterized by latency periods which are significantly shorter or longer than observed minimum or maximum latency periods, are probably not related to radiation exposure and should be excluded based upon reliable scientific data. In fact, on the basis of numerous epidemiological studies, the NIH study concluded that cancers (other than leukemia and bone cancer) with latency periods less than five years were not caused by radiation exposure.[18] This regime stands in contrast to that contained in the National Vaccine Injury Compensation Program which sets out a time period between vaccine administration on the onset of the first symptom or manifestation of the disease.

In summary, S. 1994 would permit compensation for cancers whose causal relationship to radiation is dubious. The bill's criteria would allow awards where the doses are probably too low to cause most of the cancers specified as compensable, according to the congressionally-mandated NIH report. The criteria take no account of more plausible cancer-causing agents, such as tobacco. They permit no analysis of latency periods, which would reliably isolate cancers unrelated to radiation exposures.

Under S. 1994, a petitioner would be entitled to compensation upon a finding "on the record as a whole that the petitioner has shown the matters required under subsection 2142(c)(1)." There is no standard of proof set forth in the bill nor any requirement for a affirmative finding of causation. Even the National Childhood Vaccine Injury Compensation Program requires these findings to support compensation awards.

The apparent rationale for providing special compensation to miners, rather than workers in all strategic industries who have suffered occupational illnesses, is that the miners labored in private mines which "were providing uranium for the sole use and benefit of the nuclear weapons program of the United States Government . . . ."[19] (Emphasis supplied.) The bill, however, would compensate miners who worked in all of the uranium mines in

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[18] Id., at 59.

[19] Section 2(3).

Colorado, New Mexico, Arizona, and Utah between 1947 and 1971, when only a portion of the uranium mined in these states during that time period was used in the nuclear weapons program. Further, each state's worker compensation scheme makes compensation available for miners' injuries on the job including radiation related injuries. In short, the miners already have a remedy available to them.

The bill's criteria for compensating the uranium miners, like the criteria for compensating those allegedly exposed to fallout, contain no provision for analyzing latency periods. Thus, a miner with a lung cancer latency period of one year would be paid, despite the clear scientific consensus that so short a time between exposure and diagnosis is incompatible with a finding that the cancer was caused by radiation.[20]

S. 1994 also would compensate miners who have contracted "other serious respiratory disease(s)."[21] The National Academy of Science BEIR IV Committee review of the epidemiological studies which have considered nonmalignant respiratory diseases among miners reveals that the studies are inconsistent in their findings, plagued by insufficient data, and do not assess the effects of other harmful agents to which miners are exposed.[22]

In short, we are strongly opposed to S. 1994 in its current form because it would establish a broad, unjustified, and expensive entitlement program based upon a Claims Court model that has suffered from significant practical problems. Moreover, the decision-making structure of S. 1994 raises serious constitutional questions. We appreciate your consideration of our views.

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[20] Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables, at. p. 59.

[21] Subsection 2142(c)(1)(A)(ii)(III).

[22] "Health Risks of Radon and Other Internally Deposited Alpha-Emitters" (BEIR IV), National Academy Press (1988), pp. 489-90.

The Office of Management and Budget has advised that there is no objection to the presentation of this report and that enactment of S. 1944 would not be in accord with the program of the President.

Sincerely,

Bruce C. Navarro
Acting Assistant Attorney General

U. S. Department of Justice

Washington, DC 20530

Honorable Joseph R. Biden, Jr.
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

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[7] Id.

[8] Section 2(1).

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> Two groups of children -- one group of 2,691 residing in a relatively high fallout area of Utah and Nevada, and another group of 2,140 in a minimal fallout area of Arizona during their infancy and early childhood -- were compared by Rallison and co-workers for evidence of thyroid disease. Benign neoplasms were observed in 6 exposed and 10 nonexposed children. Two carcinomas were found, but only in the nonexposed children, 15-20 years after the fallout period.[12]

An increase in leukemia among residents in the Utah counties nearest the test site has been detected. However, the association of this increase with fallout exposure is ~~suspect~~ uncertain because there was a coexistent increase noted in a type of leukemia unrelated to radiation exposure. ~~Moreover,~~ There was a similar increased leukemia incidence which occurred even prior to the use of the Nevada Test Site. ? Accordingly, the NIH experts concluded that, for persons over age 50 at the time of diagnosis, "(t)hese observations suggest the possibility of a generally elevated leukemia risk in southwestern Utah, unrelated to fallout exposure."[13]

An increase in childhood leukemia also was detected, ~~but~~ The researchers noted "that there were only 12 childhood deaths from leukemia in southwestern Utah during 1950-1980," which they regarded as "unremarkable in terms of rates for Utah as a whole." The experts also gave a number of reasons for cautioning against the assumption that the increase was necessarily attributable to radiation exposure.[14]

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[11] Id., at 53.

[12] "The Effects on Population of Exposure to Low Levels of Ionizing Radiation: 1980" (BEIR III), National Academy Press, p. 300. This study is now being updated by the original investigators at the University of Utah.

[13] Machado, et al., at 55.

Downwinders compensation under S. 1994 would depend upon only three criteria: (1) the claimant lived in certain counties of Utah, Nevada, or Arizona, (2) during particular time periods, and (3) contracted a specific disease. These general criteria would allow the compensation of persons whose diseases are probably unrelated in any way (setting aside even a proximate causation standard) to any asserted radiation exposures.

The criteria also would allow compensation of persons who contracted lung, female breast, stomach, colon, esophageal, and urinary tract cancer, regardless of the radiation dose they received. The NIH study, which was intended by Congress to quantify the association of cancer with radiation doses, ~~plainly~~ demonstrated that these cancers are probably unrelated to the low doses received by persons who lived in the test site vicinity.[15] Even assuming the exaggerated doses calculated by plaintiff's consultant in the Allen litigation,[16] a causal relationship between these diseases and the plaintiffs' asserted doses is improbable according to the NIH study.[17] This is the very study mandated by Congress to examine the exact issues raised by S. 1994.

The criteria also take no account of more plausible proximate causes of diseases such as lung and colon cancer. Thus, a heavy smoker, predisposed to lung cancer, and a person with a high fat-low fiber diet, predisposed to colon cancer, could receive the same payments as any other member of the group defined by the bill, irrespective of the improbable proximate relationship between their radiation doses and the particular diseases that they have contracted.

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[14] Id., at 55.

[15] See references cited in American Journal of Epidemiology, supra, at 46. See also, L.R. Anspaugh and B. W. Church, "Historical Estimates of External Gamma Exposure and Collective External Gamma Exposure from Testing at the Nevada Test Site," Health Physics, Vol. 51, No. 1, p. 35.

[16] The doses calculated by plaintiffs' expert witness, John Gofman, and by the other experts are noted in Allen v. United States, 588 F. Supp. 247, 428 (1984).

[17] Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables, at pp. 126 et seq.

The criteria also are deficient in permitting no analysis of a claimant's latency period -- the time period between radiation exposure and diseases diagnoses. Such an analysis is typically useful because cancers, characterized by latency periods which are significantly shorter or longer than observed minimum or maximum latency periods, are probably not related to radiation exposure and should be excluded based upon reliable scientific data. In fact, on the basis of numerous epidemiological studies, the NIH study concluded that cancers (other than leukemia and bone cancer) with latency periods less than five years were not caused by radiation exposure.[18] This regime stands in contrast to that contained in the National Vaccine Injury Compensation Program which sets out a time period between vaccine administration on the onset of the first symptom or manifestation of the disease.

In summary, S. 1994 would permit compensation for cancers whose causal relationship to radiation is dubious. The bill's criteria would allow awards where the doses are probably too low to cause most of the cancers specified as compensable, according to the congressionally-mandated NIH report. The criteria take no account of more plausible cancer-causing agents, such as tobacco. They permit no analysis of latency periods, which would reliably isolate cancers unrelated to radiation exposures.

Under S. 1994, a petitioner would be entitled to compensation upon a finding "on the record as a whole that the petitioner has shown the matters required under subsection 2142(c)(1)." There is no standard of proof set forth in the bill nor any requirement for a affirmative finding of causation. Even the National Childhood Vaccine Injury Compensation Program requires these findings to support compensation awards.

The apparent rationale for providing special compensation to miners, rather than workers in all strategic industries who have suffered occupational illnesses, is that the miners labored in private mines which "were providing uranium for the *sole use and benefit of the nuclear weapons program* of the United States Government . . . ."[19] (Emphasis supplied.) The bill, however, would compensate miners who worked in all of the uranium mines in

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[18] *Id.*, at 59.

[19] Section 2(3).

Colorado, New Mexico, Arizona, and Utah between 1947 and 1971, when only a portion of the uranium mined in these states during that time period was used in the nuclear weapons program. Further, each state's worker compensation scheme makes compensation available for miners' injuries on the job including radiation related injuries. In short, the miners already have a remedy available to them.

The bill's criteria for compensating the uranium miners, like the criteria for compensating those allegedly exposed to fallout, contain no provision for analyzing latency periods. Thus, a miner with a lung cancer latency period of one year would be paid, despite the clear scientific consensus that so short a time between exposure and diagnosis is incompatible with a finding that the cancer was caused by radiation.[20]

S. 1994 also would compensate miners who have contracted "other serious respiratory disease(s)."[21] The National Academy of Science BEIR IV Committee review of the epidemiological studies which have considered nonmalignant respiratory diseases among miners reveals that the studies are inconsistent in their findings, plagued by insufficient data, and do not assess the effects of other harmful agents to which miners are exposed.[22]

In short, we are strongly opposed to S. 1994 in its current form because it would establish a broad, unjustified, and expensive entitlement program based upon a Claims Court model that has suffered from significant practical problems. Moreover, the decision-making structure of S. 1994 raises serious constitutional questions. We appreciate your consideration of our views.

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[20] Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables, at. p. 59.

[21] Subsection 2142(c)(1)(A)(ii)(III).

[22] "Health Risks of Radon and Other Internally Deposited Alpha-Emitters" (BEIR IV), National Academy Press (1988), pp. 489-90.

The Office of Management and Budget has advised that there is no objection to the presentation of this report and that enactment of S. 1944 would not be in accord with the program of the President.

Sincerely,

Bruce C. Navarro
Acting Assistant Attorney General

ATTACHMENT

21

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date	April 5, 1991
From	Annette McLaughlin Annette McLaughlin Dr. Richard Adamson's Office
Subject	NCI Thyroid/Iodine-131 Assessments Committee
To	Dr. Wachholz/Lorraine

Dr. Howell spoke with you yesterday requesting information needed to be included in the memorandum to Dr. Broder. I have attached a note and a memo to Peggy Yasem which state the information that is required to be included. Please prepare a statement that will be added to the attached letter which includes why at least 17% minority representation and 23% female representation has not been met, as well as status of remaining candidate for this Committee.

If you have any questions, please call me.

DEPARTMENT OF HEALTH & HUMAN SERVICES
National Institutes of Health
National Cancer Institute

Memorandum

Date March 11, 1991

From Director, DCE, NCI

Subject Nomination for the NCI Thyroid/Iodine-131 Assessments Committee, Division of Cancer Etiology

To Dr. Samuel Broder
Director, National Cancer Institute

The NCI Thyroid/Iodine-131 Assessments Committee assists the Director, National Cancer Institute, and the Secretary of Health and Human Services in responding to Section 7(a) of Public Law 97-414 which directed the Secretary of Health and Human Services to: (1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131; (2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of dine-131 that are received by individuals from nuclear bomb fallout; and (3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests.

	TERM	EXPERTISE
BECKER, David V., M.D. Director Division of Nuclear Medicine The New York Hospital Cornell Medical Center 525 East 68th Street - L205 New York, New York 10021	Immediately- 06/30/93	Nuclear Medicine
BOOK, Steven A., Ph.D. Chief, Health Hazards Division Department of Health Services State of California 714 P Street, Room 460 Sacramento, CA 95814	Immediately- 06/30/93	Radioiodine Metabolism/Thyroid Gland Radiobiology
LAND, Charles E., Ph.D. Health Statistician Division of Cancer Etiology National Cancer Institute Executive Plaza North - Room 408 Bethesda, MD 20892	Immediately- 06/30/93	Health Statistics

MACHTA, Lester, Sc.D. Air Resources Laboratory National Oceanographic and Atmospheric Administration 8060 13th Street Silver Spring, MD 20910	Immediately- 06/30/93	Atmospheric Res.
MARKS, Sidney, M.D., Ph.D. 8024 47th Place, West Mukilteo, WA 98275	Immediately- 06/30/93	Radiat. Pathology
ROBBINS, Jacob, M.D. Chief, Clinical Endocrinology Branch National Institute of Diabetes & Digestive & Kidney Diseases Building 10, Room 8N315 Bethesda, MD 20892	Immediately- 06/30/93	Endocrinology
SILVERMAN, Charlotte, M.D. Associate Director for Human Studies Office of Science and Technology Center for Devices and Radiological Health Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	Immediately 06/30/93	Epidemiology
VOILLEQUE, Paul G. Technical Advisor (Health Physicist) Utility Services Department Science Applications International Corporation Idaho Falls, Idaho 83402	Immediately- 06/30/93	Environmental Transport of Radionuclides/ Radiation Dose Assessment
WACHHOLZ, Bruce W., Ph.D. Chief Low-Level Radiation Effects Branch National Cancer Institute Executive Plaza North, Room 530 Bethesda, Maryland 20892	Immediately- 06/30/93	Radiation Biology
WALINDER, Gunnar Olov S., Ph.D. Director Unit of Radiological Oncology The Swedish University of Agricultural Sciences P. O. Box 7031 S-750 07 Uppsala, Sweden	Immediately- 06/30/93	Radiation Biology/Tumor Pathology

Richard H. Adamson, Ph.D.

APPROVED: ______________________________ __________
Director, National Cancer Institute Date

Attachments:
ACR
CV
Proposed Plan for Balance

cc:
CMO/NCI
CMO/NIH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

FACSIMILE TRANSMISSION

DIVISION OF CANCER ETIOLOGY
OFFICE OF THE DIRECTOR

DATE March 11, 1991

TO: Dr. Wachholz/Lorraine

FAX NO.:

FROM: Annette McLaughlin

FAX NO.: (301) 496-1297

VOICE NO. FOR VERIFICATION: (301) 496-6618

NO. OF PAGES (INCLUDING COVER PAGE) 7

COMMENTS: We need to include in the attached memorandum the ~~following information:~~
"Need to address the two remaining vacancies. Mention Brill, of course, and who you are targeting ~~for the~~ remaining positions. Also, were any minorities and additional female candidates sought and found, if not state this please."

~~page 3?~~
~~who the other~~
~~persons~~

Roster
- donot add Brill

WORKSHEET

Committee: NCI-Thyroid/Iodine-131 Assess.
Executive Secretary: Dr. David Howell
Effective Date: Immed. - 6/30/93
Date Reviewed: February 8, 1991

Membership:

	Current	Proposed
Authorized:	12	12
Active:	0	10
Vacant:	12	2
Females	0	1(8.3%)
Minorities	0	0

COMMENTS:

Members will serve until task is completed. An ACR for Dr. Brill has been submitted to NIH/CMO and once clearance is received a nomination package will be submitted.

Geographical Distribution:

EAST	0	1 (8.3%)
SOUTH	0	5 (42%)
CENTRAL	0	1 (8.3%)
WEST	0	2 (16%)
FOREIGN	0	1 (8.3%)

Multiple States:	No.
Maryland	5

NOTE: REMINDER - NEED JUSTIFICATIONS FOR DEPT. APPROVAL: Lack of Year's Lapse; Dual Membership (service on two committees concurrently); Unbroken Service Exceeding Four Years; Excessive Service (more than eight years for the past 12 years); Two Members from the Same Institution. Less than 23% female Representation and/or less than 17% minority representation.

Proposed Annual Rotation:

1991		1992		1993		1994		1995
0	+	0	+	11	+	0	+	0

Other Comments:

REVISED CMO/NCI-10/25/90

PROPOSED PLAN FOR APPROPRIATE BALANCE -- NCI THYROID/IODINE-131 ASSESSMENTS COMMITTEE

Authorized Positions -- 12

NAME	TERM ENDING	EXPERTISE	PROF/ LAY*	STATE	MINORITY	FEMALE
D. Becker	06/30/90[+]	Nuclear Medicine	P	NY		
S. Book	04/04/90[+]	Radioiodine Metabolism/ Thyroid Gland Radiobiology	P	CA		
C. Land	07/09/90[+]	Health Statistics	P	MD		
L. Machta	03/11/90[+]	Atmospheric Research	P	MD		
S. Marks	03/03/90[+]	Radiation Pathology	P	WA		
J. Robbins	03/10/90[+]	Endocrinology	P	MD		
C. Silverman	03/04/90[+]	Epidemiology	P	MD		X
P. Voilleque	07/30/90[+]	Environmental Transport of Radionuclides/Radiation Dose Assessment	P	ID		
B. Wachholz**	06/30/90[+]	Radiation Biology	P	MD		
G. Walinder	09/29/90[+]	Radiation Biology and Tumor Pathology	P	SWEDEN		
ACR PENDING						
A. Bertrand Brill	06/30/93	Nuclear Medicine/Radiology	P	MA		

*Due to technical nature of committee, lay representation is inappropriate.
**Chairman
[+] Waiver to Allow Reappointment to NCI Thyroid/Iodine-131 Assessments Committee approved 8/7/90 (see attached)

February 13, 1991

NOTE TO: Peggy Yassem

FROM: Committee Management Office, NCI

SUBJECT: Nominations for the NCI Thyroid/Iodine-131 Assessments Committee

I have reviewed the nomination package you submitted on Friday, February 8th, for the NCI Thyroid/Iodine-131 Assessments Committee. While most of the submission was appropriate, there are minor revisions and clarifications needed prior to final transmittal to Dr. Broder for approval. A listing of revisions is as follows:

- Ensure that the addresses/current positions listed in the cover memorandum agree with the addresses/current positions provided on the resumes and ACRs.
- List each nominee's professional degree in the cover memorandum.
- An actual resume is needed for Dr. Walinder.
- The discussion paragraph(s) must appear at the beginning of the memorandum and should be expanded to address the following points:

  1. Lack of a minority candidate
  2. Under representation of female members

  It is the NIH's goal to have at least 17% minority representation and 23% female representation on all chartered committee.

  3. Approval of a waiver for unbroken service exceeding four years
  4. Consideration given to the geographic balance
  5. Status of the remaining vacancy - for example, "candidate has been selected and an ACR has been submitted. Once clearance is received, a nomination package will be provided for your approval."

- If there are any questions or additional assistance is needed, please call the Committee Management Office at 496-5708.

Carol A Frank

Carole A. Frank

ATTACHMENT

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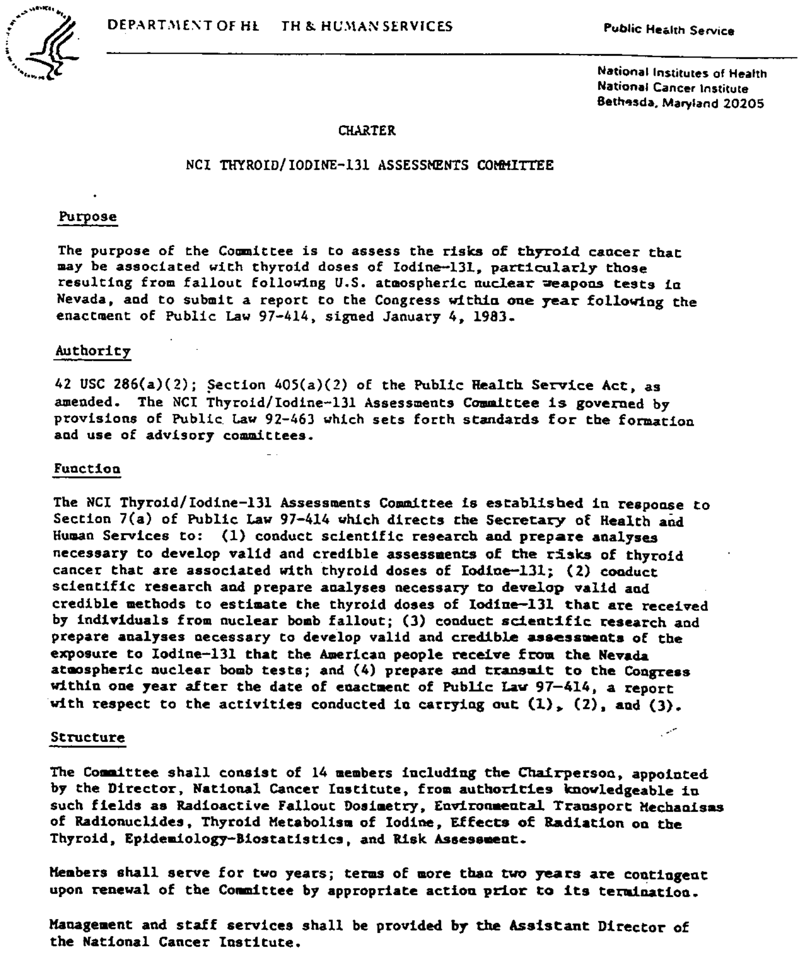

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20205

CHARTER

NCI THYROID/IODINE-131 ASSESSMENTS COMMITTEE

Purpose

The purpose of the Committee is to assess the risks of thyroid cancer that may be associated with thyroid doses of Iodine-131, particularly those resulting from fallout following U.S. atmospheric nuclear weapons tests in Nevada, and to submit a report to the Congress within one year following the enactment of Public Law 97-414, signed January 4, 1983.

Authority

42 USC 286(a)(2); Section 405(a)(2) of the Public Health Service Act, as amended. The NCI Thyroid/Iodine-131 Assessments Committee is governed by provisions of Public Law 92-463 which sets forth standards for the formation and use of advisory committees.

Function

The NCI Thyroid/Iodine-131 Assessments Committee is established in response to Section 7(a) of Public Law 97-414 which directs the Secretary of Health and Human Services to: (1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine-131; (2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine-131 that are received by individuals from nuclear bomb fallout; (3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine-131 that the American people receive from the Nevada atmospheric nuclear bomb tests; and (4) prepare and transmit to the Congress within one year after the date of enactment of Public Law 97-414, a report with respect to the activities conducted in carrying out (1), (2), and (3).

Structure

The Committee shall consist of 14 members including the Chairperson, appointed by the Director, National Cancer Institute, from authorities knowledgeable in such fields as Radioactive Fallout Dosimetry, Environmental Transport Mechanisms of Radionuclides, Thyroid Metabolism of Iodine, Effects of Radiation on the Thyroid, Epidemiology-Biostatistics, and Risk Assessment.

Members shall serve for two years; terms of more than two years are contingent upon renewal of the Committee by appropriate action prior to its termination.

Management and staff services shall be provided by the Assistant Director of the National Cancer Institute.

Meetings

Meetings shall be held at least two times a year at the call of the Chairperson, with the advance approval of a Government official who also approves the agenda. A Government official must be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary. Public notice of all meetings shall be provided.

Meetings shall be conducted and records of the proceedings kept as required by applicable laws and Departmental regulations.

Compensation

Members who are not Federal employees may be paid up to $150 per day for time spent at meetings, plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is $36,620.

Estimate of annual person years of staff support required is 1.0, at an estimated annual cost of $27,521.

Reports

A report shall be submitted to the Director, National Cancer Institute, not later than November 30 of each year, which shall contain, as a minimum, a list of members and their affiliations, with addresses; the Committee's functions, dates and places of meetings, and a summary of activities and/or recommendations of the Committee during the year.

Termination

The NCI Thyroid/Iodine-131 Assessments Committee will terminate two years from the date of establishment unless extension beyond that date is appropriately requested and approved.

Formal Determination

By authority vested in me by the National Cancer Act of 1971, P.L. 92-218, as amended, I hereby determine the formation of the NCI Thyroid/Iodine-131 Assessments Committee is in the public interest in connection with the duties imposed on the Director, National Cancer Institute, by law and that such duties can best be performed through the advice and counsel of such a group.

I further deem that: (1) it is not feasible for the NCI or any of its existing committees to perform these duties; and (2) the membership of this Committee which exceeds the 12-member limit prescribed by General Services Administration Regulations, 41 CFR §101-6.1009(b)(4), is necessary to the function of the Committee.

JUN 12 1984
Date

Vincent T. DeVita, Jr., M.D.
Director, National Cancer Institute

ATTACHMENT

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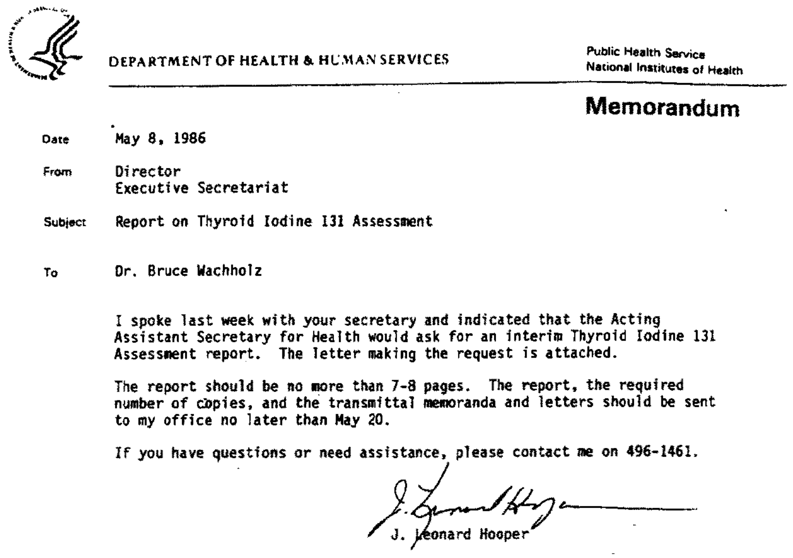

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date May 8, 1986

From Director
Executive Secretariat

Subject Report on Thyroid Iodine 131 Assessment

To Dr. Bruce Wachholz

I spoke last week with your secretary and indicated that the Acting Assistant Secretary for Health would ask for an interim Thyroid Iodine 131 Assessment report. The letter making the request is attached.

The report should be no more than 7-8 pages. The report, the required number of copies, and the transmittal memoranda and letters should be sent to my office no later than May 20.

If you have questions or need assistance, please contact me on 496-1461.

J. Leonard Hooper

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date MAY 6 1986

From Acting Assistant Secretary for Health

Subject Report to the Congress: Analysis of Thyroid Cancer in Relation to Iodine-131 Exposure

To Director
National Institutes of Health

The report on Analysis of Thyroid Cancer in Relation to Iodine-131 Exposure, a report mandated by P.L. 97-414, the Orphan Drug Act, was due to the Congress in January 1984. An interim report was submitted to the Office of the Secretary in August 1984, but not to the Congress.

In order to keep the Congress apprised of progress on the required research and assessments, periodic reports should be submitted to the Congress. I am, therefore, asking that NIH submit a brief progress report by May 23.

The report should be submitted by May 23 to the PHS Congressional Reports Coordinator, Office of Health Planning and Evaluation, OASH.

Donald Ian Macdonald, M.D.

Note to: Dr. Adamson

Date : May 30, 1986

A report to the Congress on this matter left my office in November, 1983. It never was transmitted to the Congress by OS.

Since a comprehensive analysis and assessment report of the current state-of-the-art re the areas addressed by P.L. 97-414, Section 7(a), will be submitted later this year for transmittal to the Congress (of which Mr. Hooper is well aware), it seems a bit awkward to send a brief report now and a more complete technical report in less than a year.

Would it be in order to suggest, in view of the comprehensive forthcoming report, to dispense with this one? I suggested this to Mr. Hooper, but he was not receptive to it.

B

Bruce W. Wachholz

ATTACHMENT

24

I-131 Fallout Report and Collateral Activities Chronology

Table of Content

HISTORY
1951-62

A. Congressional Hearing on fallout included some I-131 exposure
Excerpts from Hearing re: Fallout, Radiation Standards, and Countermeasures (1957 - 1963)

1960's

B. PHS conducted a study on children
C. The cohort was re-studies in 1980's through the Univ. of Utah
D. Report from Lawrence Laboratory
5/10/66 Report on estimated thyroid doses to children from Nuclear Tests Conducted in Nevada During 1952 - 1955

1970's

E. Multiple studies were undertaken to study childhood leukemia in Utah

CHRONOLOGY
1982

F. The Orphan Drug Act was amended
1/4/83 P.L. 97-414, Orphan Drug Act

G. Sen. Hatch initiated this action through HHS
H. Contract awarded by NCI to Univ. Of Utah to assess leukemia & thyroid in relation to fallout in Utah
I. Extensive efforts were made to evaluate thyroid function and reconstruct I-131 exposure

1983

J. Dr. Wachholz assumed responsibility for this contract in May 1983
K. Orphan Drug Act signed January 4 (P.L. 97-414)

L/O. NCI's Radiation Effects Branch following the appointment of a Branch Chief (Bruce W. Wachholz) in May
    1983 Draft Report to Congress on Thyroid/I-131 Assessments Per Section 7 (a), P.L. 97-414.
    8/8/86 Memo from Chief, Radiation Effects Branch to Director, DCE, NCI re: Reference Made to LLREB Chairing a "Thyroid Committee"

M. Sen. Hatch met with Dr. Wachholz to discuss working group participants
N/P. Advisory Committee was established on an ad hoc basis
    9/6-7/83 Minutes of the meeting of the Ad Hoc Working Group on Thyroid/I-131 Assessments

1984

Q. NCI recognized to obtain services of an expert in the deposition and environmental transport of radionuclides in fallout
R. Andres Bouville joined REB to serve as senior staff scientist
S. NIH forwarded draft report to the DHHS for Secretary's signature to be transmitted to Congress
T. P.L. 98-542 directed that a review of the reliability and technical devices which may be useful in determining previous radiation
    10/24/84 P.L. 98-542, Veterans Dioxin & Radiation Exposure Compensation Standard Act
    10/30/84 Letter to Rep. Montgomery from Sec. HHS, re: Delegation

U. Reports were submitted to Congress and VA in August 1987
V. Branch Chief was one of two HHS representatives to serve on the Science Panel
W. Overview of REB activities at the Board of Scientific Counselors
    10/18/84 Minutes re: BSC meeting

X. Advisory Committee formally chartered with 12 members who were authorities in dosimetry, environmental transport of radionuclides
    5/24/84 Notice of Establishment of the NCI Thyroid/I-131 Assessments Committee
    6/12/84 Charter of the NCI Thyroid/Iodine-131 Assessments Committee

1985

Y. Estimating exposures was presented to Advisory Committee

Z. Cooperation established with other Federal Agencies (NOAA, Commerce, DoE, USDA)

AA. NCI began collaboration with Swedish scientists at Karolinska Institute

BB. Presentation of the legislative mandate (P.L. 97-414)
10/17/85 Minutes re: BSC meeting, presenting the I-131 study & Assessments Committee

1986

CC. Methodology accepted by Advisory Committee

DD. Interim report to Congress and cover letters transmitted to Bldg. 1.
10/23/86 Memo from Assistant Secretary of Health to The Secretary re: Transmittal of Report to the Congress on Thyroid/Iodine-131 Assessments ----Action

EE. The Chernobyl accident occurred April 26

FF. Dr. Bouville participated in the preparation of a report on the accident for the United Nations

GG. Presentation of REB radiation activities at the BSC
2/21/86 Agenda & minutes re: BSC meeting

HH. Presentation of mandate for studies of exposure and risk at BSC
6/12/86 Agenda & minutes re: BSC meeting

II. DCE Annual Report included reference to I-131 project
10/85-9/86 1986 Annual Report of Low Level Radiation Effects Branch

1987

JJ. Fallout I-131 and transfer of I-131 was achieved on all aspects of the project

KK. Five papers were presented at the annual meeting of the Health Physics Society
5 papers, referenced

LL. Chernobyl led to extensive planning for animal studies

MM. DCE Annual Report included reference to I-131 Report

10/86-9/87 1987 Annual Report of The Radiation Effects Branch Chemical

KK. Five papers were presented at the annual meeting of the Health Physics Society

NN. Advisory Committee briefed on the consequences of the Chernobyl accident

8/25/87 Minutes of NCI Thyroid -131 Assessments Committee

1988

OO. Most data to determine the I-131 concentrations in milk were collected

PP. One technician was hired to help with the computer work

QQ. Two papers were presented at the International Association of Radiation Protection meeting

RR. DCE Annual Report included reference to of I-131 project

10/87-9/88 1988 Annual Report of The Radiation Effects Branch

1989

SS. The outline and content of the report to Congress were determined

TT. Collection of precipitation data was completed

UU. First estimates doses made for nuclear tests for which complete information was available

VV. Initial draft of the report was presented and discussed

WW. Two papers were presented at the annual meeting of the Health Physics Society

XX. A second technician was hired to help the computer work

YY. Scientific assistant accepted position at International Atomic Energy Agency and let the project

ZZ. Request was made for I-131 data pertaining to Hanford, WA region

A1. DCE Annual Report included reference to I-131 project

10/88-9/89 1989 Annual Report of The Radiation Effects Branch

A2. DCE BSC was presented a status update on I-131 project

11/17/89 Cancer Letter re: I-131 Doses Highest Near Neveda Test Site.

1990

A3. Draft report sent to outside reviewers for comments

A4. Systematic preparation of Annexes, with large number of text files, was undetaken

A5. Decision made by NCI to prepare subannexes of data and formulae to be useful

A6. DoE asked NCI to take responsibility to plan for and work with Soviet Union scientists to develop long-term studies of health effects from Chernobyl nuclear power plant accident

A7. DoE suggested Dr. Wachholz to manage program

A8. Work began in collaboration with other US agencies and international organizations

A9. Drs. Wachholz and Bouville participated in the International Chernobyl Project

A10. Final results submitted from Utah study

A11. DCE Annual Report included reference to I-131 project
10/89-9/90 1990 Annual Report of The Radiation Effects Branch

A12. June discussion of animal studies to determine thyroid cancer risk from I-131 exposure at DCE BSC
6/21/90 Minutes of the BSC

1991

A13. All initial calculations leading to results that were to be included in Main Test or Appendices were carried out
A14. Work continued on: revision on Main Text; verification of numerical results; systematic preparation of Annexes
A15. The Appendix justifying the assumption that all I-131 was fixed on particles was undertaken
A16. Interim report to Congress on thyroid/I-131 assessments prepared by NCI for Secretary's signature and transmittal to Congress
6/21/91 Memo from Bruch Wachholz to Dr. Broder re: Transmittal of Report to the Congress on Thyroid/I-131 Assessments

A17. Between 1991-1993, negotiations with new governments in Belarus and Ukraine were required following dissolution of USSR
A18. Other groups in contact included WHO (Geneva & European Offices)
A19. DCE Annual Report included reference to I-131 project
10/90-9/91 1991 Annual Report on the Radiation Effects Branch

1992

A20. Main text was revised, with exception of two chapters
A21. Main text was retyped using WordPerfect
A22. Most of the numerical results were checked.
A23. Appendix justifying assumption that all I-131 was fixed on particles was finished
A24. All calculations and the systematic preparation of Annexes was completed
A25. Preliminary work was undertaken on the Subannexes
A26. Dr. Bouville moved to Bethesda campus
A27. DCRT provided storage and calculation space not available at NY facility
A28. Contract for technicians terminated, Drs. Wachholz and Bouville divided time between I-131 project and other Branch activities
A29. Final results from Utah study report between radioiodines & the thyroid neoplasms
A30. DCE Annual Report included reference to I-131 project
10/91-9/92 1992 Annual Report of Radiation Effects Branch

A31. Implementation of interagency agreement for Chernobyl studies

1993

- A32. Preliminary calculations of average doses confirmed
- A33. Most computer files from NY facility transferred to NIH
- A34. Test done at DCRT to print some of the subannexes; did not work
- A35. Mapping software deleted after computer crash
- A36. Advisory Committee heard formal presentation of estimated results; no recommendations were made
- A37. Advisory Committee terminated as scheduled by 1991 charter extension
  9/21/93 Memo from Susan Feldman to Department Committee Management Officer re: Termination of the NCI Thyroid/Iodine - 131 Assessments Committee

- A38. Scientific field focus shifted to Chernobyl while multiple countries negotiated research opportunities
- A39. Cohort study protocol for Belarus agreed upon by working groups
- A40. Belarus thyroid protocol peer-reviewed by NCI in June
- A41. Efforts to reconstruct exposure of thyroid study cohorts
- A42. Ad hoc working group participated and provided guidance regarding Chernobyl-related activities
- A43. DCE Annual Report included reference to I-131 project
  10/92-9/93 1993 Annual Report on Radiation Effects Branch

- A44. Utah study findings published in scientific literature
  11/3/93 -Use Bibliographic Citation

- A45. March presentation of Chernobyl project at DCE BSC
  10/14/93 Excerpt of Minutes of BSC

1994

- A46. First draft of the entire Main Text, Appendices, and Annexes completed in Oct.
- A47. Computer files written on CD-ROMs were uploaded onto DCRT computer
- A48. Information was reported in scientific arena in 1994 and 1995
- A49. Articles were prepared and presented
- A50. Protocol for Ukraine study approved by Ukraine & US working groups
- A51. Ukraine thyroid protocol peer-reviewed by NCI in February.
- A52. Formal agreements between US and Belarus signed in May for thyroid study
- A53. Extensive travel (4-6 trips each) required of Drs. Wachholz and Bouville to effect these activities
- A54. Dr. Steven McDonough from North Dakota requested I-131 data for 5 weapons test for all North Dakota and Utah. Sen. Dorgan requested a review of Dr. McDonough's report.
- A55. NCI staff met with Sen. Dorgan, Dr. McDonough, and DoE staff to discuss report and further research
  12/16 Ms. Duane's personal notes from briefing for Sen. Dorgan

A56. DCE Annual Report included reference to I-131 project
10/93-9/94 1994 Annual Report of Radiation Effects Branch

A57. January presentation ~~of methodologies and~~ draft map at NATO meeting in Austria
5/95 Bibliography Citation

A58. November presentation at CDC international workshop on environmental dose reconstruction
A59. Preliminary draft map presented to the Health Physics Society meeting in San Francisco

1995

A60. Subannexes computer-complete by early 1995. Printing task begun
A61. Senior staff member (Masnyk) was detailed in October to assist with the Chernobyl research project
A62. Ukraine leukemia study negotiations underway
A63. Pilot runs of procedures in Belarus
A64. Extensive travel (6-8 trips each) required of Drs. Wachholz and Bouville to effect these actions
A65. Interagency management and funding issues led to perception of project difficulties by Ukraine and Belarus
A66. Another study in collaboration with scientists in Slovenia and Israel
A67. March presentation of I-131 project at DCE BSC
3/10/95 Agenda & Minutes from BSC meeting.

A68. DCE Annual Report included reference to I-131 project
10/94-9/95 1995 Annual report of Radiation Effects Branch ~~Chemical and Physical Carcinogenesis Program~~

A69. April presentation of invited paper on reconstructing doses at annual meeting of the NCRP
4/12-13/95 Bibliography Citation

A70. Summary report of Chernobyl studies requested by Deputy Director, NCI. I-131 activities were provided as background
9/22/95 Executive Summary from Bruce Wachholz to Deputy Director, NCI re: Continued Support for NCI Involvement in Studies in Belarus and Ukraine Related to Exposures to Radiation and Radioactive Fallout from the Chernobyl Nuclear Power Plant Accident.

1996

A71. Dr. Masnyk was formally transferred to the REB, and took over major portions of the Chernobyl activity
A72. An internal final review of the I-131 complete text was begun and a decision made to release the report
A73. Reviewers had looked at technical content of all or portions of the report
A74. Ukraine leukemia protocol peer-reviewed at NCI & approved by OPRR
A75. Formal agreement between US and Ukraine signed in Oct. For leukemia study
A76. Pilot runs of procedures completed in Ukraine
A77. Extensive travel (4-6 trips each) required of Drs. Wachholz and Bouville to assure Belarus and Ukraine of US commitment
A78. DoE's purchasing agent for equipment and supplies (LLNL) withdrew support in September
A79. Request made for I-131 data pertaining to Oak Ridge, TN region
A80. Dr. Klausner conducted initial discussion of DCB programs with staff
A81. NCI answered a letter to Dr. Klausner from the Energy Research Foundation
A82. DCB budget request for FY 1997 submitted in September for $100,000 to print I-131 report
12/9/96 Funding Request for DCB for FY 1997

A83. Note from DCB to OLCA seeking advice on number of copies for printing
9/96 E-mail from Virginia Kiesewetter to Andre Bouville re: Public Reporting Requirement/Thyroid Cancer related to fall-out.

1997

A84. Final review of text and graphics continued, and revisions were made and re-reviewed; final check of the methodology, data
A85. The transfer of the remaining computer files from NY to Washington on CD ROM
A86. Preparation of over 100 maps with new software and writing new computer programs
A87. The remainder of the subannexes (80,000) were printed, and final review of all text, graphs, maps and tables took place
A88. Preparation of the entire report in electronic form and converting the remaining text into Word Perfect
A89. Full dataset to be available on the Internet October 1.
A90. Thyroid clinical examinations of cohort subjects begun
A91. March 10 Dr. Wachholz responded to CDC with a letter staring NCI's intent to release the report by Oct. 1
A92. In April, Dr. Klausner visited DCB for individual Branch
A93. In April, NCI responded to a request from Sen. Daschle regarding I-131 fallout report
4/14/97 Memo from Sen. Daschle's office to DHHS re: I-131 study

A94. June 2 NCI briefed DoE on the status of the I-131 fallout study

A95. June 27 Senate Committee on Governmental Affairs requested a briefing regarding I-131 fallout study

A96. Briefing held August 6.

A97. DoE requested a second briefing, which was held July 25

7/25/97 Ms. Duane's personal notes from DOE Briefing

A98. August 5 NCI sent follow-up letter to CDC re-stating NCI's plan to make data available by Oct. 1

8/5/97 Letter from Bruce Wachholz to Dr. Smith re: releasing the complete data base of I-131 fallout study as soon as possible.

GLOSSARY

A99. I-131 Fallout Report Includes:

(1) Main Text - methodology is presented as well as essential data and results

(2) Appendices - data that are not test-specific, such as the milk production, distribution, and consumption, or the pasture practices

(3) Annexes - data specific to each test (fallout, concentrations of I-131 in milk, etc) are presented, and average doses provided

(4) Subannexes - estimates of thyroid doses are tabulated for each test, each county of the contiguous United States, 13 ages groups, and 4 types of diet

ATTACHMENT

25

SENES Oak Ridge Inc.
Center for Risk Analysis
F. Owen Hoffman, President
Steven M. Bartell, Vice President

FAXED 5/2/96

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TO: Andre Bouville and Bruce Wachholz
National Cancer Institute
FAX NO: (301) 496-1224

FROM: F. Owen Hoffman
SENES Oak Ridge, Inc.
102 Donner Drive
Oak Ridge, TN 37830
(423) 483-6111 phone
(423) 481-0060 fax

Subject: Attached Report

Date: May 2, 1996

Pages: 19 , including this cover page

Comments:

Attached are the preliminary results and conclusions drawn from our work to date. We calculated doses for Tennessee children from the Nevada Test Site fallout that are equal to the median children in Utah. I don't have an explanation for this.

A copy of the full report is being sent to you and I would appreciate any comments.

Sincerely,

Owen

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OAK RIDGE HEALTH STUDIES
OAK RIDGE DOSE RECONSTRUCTION

A TASK 1 PRELIMINARY REPORT

FIRST ITERATION DOSE AND HEALTH RISK ASSESSMENT FOR IODINE-131 EMISSIONS FROM X-10 RADIOACTIVE LANTHANUM PROCESSING

April 1996

Submitted to the Tennessee Department of Health by

ChemRisk
A Division of McLaren/Hart

CONFIDENTIAL

This document was prepared as a team effort by the following individuals:

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Table 11.7 Results of the sensitivity analysis for the concentration in milk

Parameter	**Contribution to the uncertainty in the concentration in milk (C_m) [%]**		
	Backyard cow	Commercial cow	Goat
Source term - Q	2.8	6.8	3.0
Atmospheric dispersion - (χ/Q)	10.4	15.9	3.8
Atmospheric chemistry			
elemental to highly reactive - g_{11}	1.3	1.1	1.2
elemental to particulate - g_{12}	1.9	0.1	0.8
elemental to organic - g_{13}	3.8	0.9	<0.1
Air-to-vegetation - $AV_{elemental}$	24.2	53.1	15.5
Air-to-vegetation - $AV_{particulate}$	4.5	15.2	5.9
Air-to-vegetation - $AV_{organic}$	0.8	2.3	1.7
Pasture-to-milk - PM	50.4	4.6	68.2

Results of this analysis are presented in Tables 11.8 and 11.9 for a female child who drank milk from cows or goats grazing at 4 km and 20 km, respectively. To provide a direct comparison with the doses and risks to a female child born in 1944, results from Tables 11.1 through 11.4 are included in Tables 11.8 and 11.9.

Table 11.8 A comparison of the estimates of the total thyroid doses and risks to a female child born in 1944 and in 1952 and living at 4 km downwind of X-10.

Years of exposure	**95% subjective confidence interval for thyroid dose (cGy)***			**95% subjective confidence interval for TELR of thyroid cancer**		
	Lower Bound	**Median**	**Upper Bound**	**Lower Bound**	**Median**	**Upper Bound**
Milk from Backyard Cow						
1944-1956	7.4	83	890	1.7×10^{-4}	5.7×10^{-3}	6.8×10^{-2}
1952-1956	4.8	82	710	4.3×10^{-4}	1.1×10^{-2}	1.8×10^{-1}
Milk from Commercial Cow						
1944-1956	2.3	34	210	6.8×10^{-5}	2.0×10^{-3}	2.1×10^{-2}
1952-1956	2.2	30	230	1.5×10^{-4}	4.2×10^{-3}	5.3×10^{-2}
Milk from Goat						
1944-1956	11	180	2600	4.2×10^{-4}	1.2×10^{-2}	2.9×10^{-1}
1952-1956	9.0	230	2900	7.0×10^{-4}	3.2×10^{-2}	6.4×10^{-1}

* 1cGy = 1 rad

Table 11.9 A comparison of the estimates of the total thyroid dose and risks to a female child born in 1944 and in 1952 and living at 20 km downwind of X-10.

Years of exposure	**95% subjective confidence interval for thyroid dose (cGy)***			**95% subjective confidence interval for TELR of thyroid cancer**		
	Lower Bound	**Median**	**Upper Bound**	**Lower Bound**	**Median**	**Upper Bound**
Milk from Backyard Cow						
1944-1956	0.5	5.9	58	1.4×10^{-5}	3.6×10^{-4}	8.0×10^{-3}
1952-1956	0.5	5.4	66	3.6×10^{-5}	8.1×10^{-4}	1.4×10^{-2}
Milk from Commercial Cow						
1944-1956	0.3	2.4	23	8.9×10^{-6}	1.6×10^{-4}	2.6×10^{-3}
1952-1956	0.2	2.3	20	1.4×10^{-5}	3.5×10^{-4}	4.5×10^{-3}
Milk from Goat						
1944-1956	0.8	14	190	3.0×10^{-5}	9.0×10^{-4}	2.1×10^{-2}
1952-1956	0.7	17	214	5.1×10^{-5}	2.3×10^{-3}	4.6×10^{-2}

* 1cGy = 1 rad

The differences in the confidence intervals for the estimated thyroid doses to the two children (one born in 1944 and the other born in 1952) from the consumption of cow's milk are not significant. However, from the results of confidence intervals for the TELR of thyroid cancer to the two children, it is clear that a child born in 1952 is at increased risk for thyroid cancer as opposed to the one born in 1944. It is important, therefore, to investigate the doses and health risks to a child born in 1952 in more detail during the next iteration of the dose reconstruction study.

11.5 A Preliminary Comparison with Other Dose Reconstruction Studies

The results of this preliminary analysis for Oak Ridge can be put into perspective, by comparing it with results from other dose reconstructions performed for releases of ^{131}I. This comparison indicates that the range of doses for the Oak Ridge child at 4 km is surprisingly similar to the doses for either reference or actual children at other sites (Table 11.10). The other sites used in the comparison are the study of Utah school children exposed to Nevada Test Site (NTS) ^{131}I (Till et al., 1995; Stevens et al., 1992) and both reference and actual children exposed to ^{131}I released from Hanford (Farris et al., 1994; Kopecky, 1995). Furthermore, the doses estimated for the Oak Ridge child at 20 km are comparable with the doses estimated for a median or typical child for the other situations. These results seem somewhat counterintuitive because the releases of ^{131}I at the other sites were much greater than at Oak Ridge.

The release of ^{131}I from the NTS was nearly 5000 times greater than at Oak Ridge. However, most of the ^{131}I released from the NTS was injected into the upper atmosphere and transported for long distances. The small fraction of NTS ^{131}I deposited in southern Utah was associated with relatively insoluble large particles. These particles were not retained effectively by vegetation surfaces, and were not as readily taken up by dairy cows and secreted into milk (Stevens et al., 1992), unlike the assumptions in this analysis for RaLa ^{131}I released from X-10.

At Hanford, the release of ^{131}I was perhaps more than twenty times greater than for Oak Ridge. This large release, however, was compensated for by much greater dispersion of ^{131}I in the atmosphere. Air flow around Hanford is not constrained by the presence of valley ridges as it is at the X-10 site. In addition, the distance to the nearest residence at Hanford was almost 16 km (Ringold, WA). Furthermore, the "typical" child around Hanford was located at distances far greater than 20 km, the distance assumed in this study for the "more typical child."

Table 11.10 Comparison of uncertainty statements with other ^{131}I dose reconstruction studies

Location	**Release [Ci]**[a]	**Reference**	**95% subjective confidence interval**		**UF**[c] **[unitless]**
			Lower bound [cGy][b]	**Upper bound [cGy]**[b]	
Nevada Test Site (3545 Utah school children) maximum	1.4×10^8	Till et al. (1995)	22	2300	10
median			0.33	19	7.6
Hanford	7.3×10^5				
maximum reference child		Farris et al. (1994)	49	1,100	4.7
"typical child"			1.9	52	5.2
HTDS max of 841		Kopecky (1995)	33	477	3.9
HTDS median of 841			2.7	20	3.7
Oak Ridge Dose Reconstruction	$(2.0\text{-}5.1)\times10^4$	This study (1st iteration)			
maximum child at 4 km[d]			8.6	920	10
typical child at 20 km[e]			0.3	23	9.6

[a] 1 Ci equals 3.7×10^{10} Bq

[b] 1 cGy equals 1 rad

[c] UF = uncertainty factor, which is a ratio between the upper bound of the 95% subjective confidence bound and the 50th percentile

[d] exposed to all pathways.

[e] only consuming milk from commercial dairies.

The higher uncertainty estimates for doses calculated for children in the vicinity of Oak Ridge are primarily due to the preliminary nature of this initial assessment and the fact that our state of knowledge for many parameters is still incomplete. We expect that additional data on critical processes that dominate the overall uncertainty will effectively reduce the uncertainty estimates presented in this preliminary report. These preliminary estimates will be refined in future iterations. The high uncertainty estimates reported for the maximum child within a cohort of 3545 school children in Utah primarily reflect the

Table 11.11 Time-integrated ^{131}I concentrations in milk for four east Tennessee counties from fallout from weapons testing at Nevada Test Site (from A. Bouville, 1995).

	Nevada Test Site Test Series (dates)				
	Buster Jungle (10/28 to 11/29/51)	**Tumbler-Snapper (1/4 to 6/5/52)**	**Upshot-Knothole (3/15 to 6/4/53)**	**Teapot (2/18 to 5/15/55)**	**Plumbob (5/28 to 10/7/57)**
Milk type	**Time-integrated milk concentrations [nCi d L^{-1}] Geometric mean (Geometric standard deviation)**				
	Anderson County				
goat	48 (6.3)	2800 (2.7)	3800 (2.5)	3700 (2.4)	6100 (2.7)
backyard cow	1.3 (3.5)	280 (2.4)	350 (2.3)	350 (2.1)	590 (2.5)
commercial milk	8.7 (5.6)	240 (2.6)	230 (2.2)	240 (2.3)	280 (2.9)
	Knox County				
goat	35 (6.7)	2000 (2.1)	3600 (2.5)	2600 (2.5)	4700 (1.8)
backyard cow	1.0 (3.8)	180 (1.9)	320 (2.1)	250 (2.2)	420 (1.6)
commercial milk	6.5 (6)	170 (2)	210 (2.2)	180 (2.4)	210 (1.6)
	Loudon County				
goat	35 (6.6)	1700 (2.9)	2700 (2.7)	2600 (2.6)	5900 (2.7)
backyard cow	1.0 (3.7)	160 (2.6)	250 (2.3)	240 (2.3)	560 (2.4)
commercial milk	6.3 (6)	140 (2.7)	180 (2.3)	180 (2.5)	260 (2.5)
	Roane County				
goat	34 (6.6)	2800 (2.4)	3500 (2.6)	3200 (2.4)	4900 (3.6)
backyard cow	1.0 (3.8)	270 (2.2)	320 (2.3)	310 (2.2)	480 (3.3)
commercial milk	6.3 (5.8)	230 (2.4)	220 (2.4)	210 (2.4)	230 (3)

uncertain state of knowledge associated with the deposition of ^{131}I, its retention on vegetation, and its transfer into goat milk (Stevens et al., 1992). The low uncertainties reported for the Hanford Thyroid Disease Study (HTDS) reflect the improved state of knowledge from data obtained for specific individuals regarding their life and dietary habits and the fact that many individuals in the HTDS pilot study were on a diet of commercial as opposed to backyard cow milk (Kopecky, 1995).

11.6 Influence of ^{131}I Deposited in Tennessee from the Atmospheric Testing of Nuclear Weapons

A significant confounding source of ^{131}I exposure to the residents of Tennessee may have been fallout from the atmospheric testing of nuclear weapons. Recent data obtained from the National Cancer Institute (NCI) (Bouville, 1995) show that all counties in this state were affected by NTS fallout ^{131}I from 1951 to 1957. Using the time-integrated milk concentrations (Table 11.11) estimated by NCI for backyard cows, goats and commercial milk purchased from the store (along with estimates of uncertainty in these concentrations), we have calculated the thyroid doses and TELR of thyroid cancer to a child born in 1951 from each series of weapons testing at the NTS.

Our results are listed in Table 11.12 for Anderson, Roane, Loudon, and Knox counties. The dose and risk in three of the four counties (except Knox County) from ^{131}I deposited in NTS fallout exceed the values in Table 11.9 for exposures at 20 km to ^{131}I from RaLa processing at X-10, but are less than the values in Table 11.8 for exposures at 4 km.

We conclude that weapons fallout may have been a significant contributor to the total ^{131}I exposure for individuals located within 20 km from the X-10 site. For individuals located in valleys adjacent to Bethel Valley, who probably received doses significantly less than those who were located along Bethel valley, or for individuals located at distances beyond 20 km from X-10, weapons fallout ^{131}I may have been the dominant contributor to the total ^{131}I dose. The contribution of global ^{131}I fallout in the Oak Ridge area to the exposure received by populations in the vicinity of the X-10 facility has not yet been examined in this study.

Table 11.12 Doses and Risks from ^{131}I in Nevada Test Site fallout to a child born in 1951 in East Tennessee.

County	**Milk type**	**^{131}I thyroid dose [cGy]* (95% subjective confidence interval)**			**TELR of Thyroid Cancer (95% subjective confidence interval)**		
		lower bound	**median**	**upper bound**	**lower bound**	**median**	**upper bound**
Anderson	**goat**	8.7	63	450	$5.9x10^{-4}$	$7.3x10^{-3}$	$1.1x10^{-1}$
	backyard cow	1.2	6.7	38	$8.5x10^{-5}$	$8.5x10^{-4}$	$1.2x10^{-2}$
	commercial milk	0.8	4.7	29	$5.1x10^{-5}$	$6.1x10^{-4}$	$6.5x10^{-3}$
Knox	**goat**	6.8	45	290	$4.7x10^{-4}$	$5.3x10^{-3}$	$7.5x10^{-2}$
	backyard cow	1.0	4.3	21	$5.6x10^{-5}$	$5.7x10^{-4}$	$7.5x10^{-3}$
	commercial milk	0.6	3.4	19	$4.3x10^{-5}$	$4.4x10^{-4}$	$5.5x10^{-3}$
Loudon	**goat**	6.1	48	360	$4.3x10^{-4}$	$5.6x10^{-3}$	$9.4x10^{-2}$
	backyard cow	1.0	5.3	32	$6.2x10^{-5}$	$6.3x10^{-4}$	$9.0x10^{-3}$
	commercial milk	0.4	2.5	17	$3.0x10^{-5}$	$3.4x10^{-4}$	$4.8x10^{-3}$
Roane	**goat**	7.5	57	422	$1.3x10^{-3}$	$1.1x10^{-2}$	$8.4x10^{-2}$
	backyard cow	1.1	6.2	39	$1.9x10^{-4}$	$1.1x10^{-3}$	$7.5x10^{-3}$
	commercial milk	0.8	4.3	26	$1.3x10^{-4}$	$7.9x10^{-4}$	$5.2x10^{-3}$

* 1 cGy equals 1 rad

11.7 References

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ATTACHMENT

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02/15/96 THU 14:44 FAX 903 1413 INTERNATIONAL 002

Department of Energy
Germantown, MD 20874-1290

FEB. 15 1996

Dr. Bruce Wachholz
Chief, Radiation Effects Branch
National Cancer Institute
6130 Executive Boulevard, Rm. 530
Rockville, Maryland 20852-7391

Dear Dr. Wachholz:

Cherie Gianino and I found our trip to Minsk, Belarus, January 20-25, 1996, in which we met with the scientists and the Government officials involved in the Belarus/American (Bel/Am) Thyroid Study and visited the facilities, very informative. Our visit enabled us to gain a better understanding of the status and the needs of the project.

Following a review of our visit and detailed discussions on the long-term (30-year) Bel/Am Thyroid Study with Dr. Paul Seligman, Mr. Frank Hawkins, and the staff of the Office of International Health Programs (EH-63), we have determined that we have a number of general concerns and specific requests relating to the project. These are outlined below.

General Concerns:

- Provision of U.S. funds to Belarus for personnel support for the Byelorussians working on the Bel/Am study will result in a fundamental change in the agreement signed with the Belarus Government. This agreement and the Bel/Am Thyroid Protocol state that Belarus will support all Byelorussians working on this project. A commitment to provide Belarus personnel support also significantly increases the cost to the United States, and to the Department of Energy (DOE) in particular, at a time when DOE's budget is being cut severely. You have indicated the National Cancer Institute (NCI) is unable to provide any additional funds. Furthermore, the possibility that a portion of the $500,000 of matching NCI/DOE funds managed by the NCI can be used for Belarus personnel support has not been adequately discussed.

- The most recent budget estimates that you presented to our office for funds required for personnel support in Belarus are more than double what you presented to us several months ago. This has severely compromised our fiscal year 1996 budget projections for this project.

- The personnel needs in Belarus will escalate considerably over the next 3 years as the number of children who are actively being followed increases. No other U.S. agency has agreed to absorb any of these costs. Such a commitment has the potential of compromising all the programs supported by our office.

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- As you inferred in your January 31, 1996, letter, any financial commitments we make in Belarus will need to be repeated (in some cases on a larger scale) in the four studies that are either ongoing or being planned in Ukraine.

- We continue to be concerned about the numerous reports of delays and difficulties in moving the project forward.

- Finally, the oversight committee for this protocol, signed in May 1994, is not established. The scientific review of this protocol carried out by the NCI in 1993(?) emphasized that, "the oversight group should be established as soon as possible so that the study may benefit from the advice and guidance of an interdisciplinary and bilateral scientific body of experts." This lack of oversight is of particular concern to us because this project is such a long-term (30-year) commitment, and it does not have clearly defined stages at which milestones need to achieved and the project reassessed.

Each of these concerns has reinforced our view that we need to proceed cautiously with regard to providing direct personnel support to Belarus. That is what I did during my visit to Belarus. I regret if this has caused you any inconvenience, but it would be imprudent for our office to make long-term financial commitments that we cannot meet. As always, *our goal is to support this important project, while assuring the efficient and prudent stewardship of all U.S. funds and resources.*

Specific Requests:

In order to fulfill our budgetary and managerial responsibilities EH-63 would like the following information.

- **Progress Report.** We would like to receive a progress report for the Bel/Am Thyroid Study that includes all progress made since the signing of the protocol. In this context, we also would like to work with you and set up a future schedule for completing progress reports that would be distributed to all the agencies supporting this project.

- **Organizational Chart.** During our meetings in Belarus, Dr. Krisenko, the Belarus Project Leader, requested that we provide him with an organizational chart of the American scientists who will be working on the study. Please send us a copy of the chart including the responsibilities of each of the individuals.

- **Oversight Committee.** Dr. Krisenko noted during our group meetings in Belarus that he is anxious to convene the Advisory Committee for this project. I understand his desire, since as outlined in the protocol, the Advisory Committee was supposed to review the progress of the project at the end of the project's first year, which was in May 1995. Dr. Krisenko provided us with the list of members for the Belarus half of the Advisory Committee and requested that we submit our list of American Advisory Committee members to him as soon as possible. We would like to work with you and the NCI staff to identify who in the NCI will be in charge of putting together the initial American Advisory Committee, and to determine when that individual will consult with us on the composition of the committee.

- **Milestones/Funding Agreement for Belarus Support**. As we discussed in Geneva in November 1995, and on several occasions before and after the Geneva trip, in order for us to determine an appropriate level of funding for scientific support for Byelorussians for the first year of the project, we need a completed set of milestones that are written with clear deliverables for each of the tasks. I was quite pleased that after our discussion on January 22, 1996, the evening we arrived in Belarus, that you, Dr. Lynn Anspaugh and Dr. Andre Bouville were able to generate draft milestones for the first 3 months, which could be presented to Dr. Krisenko the next day. Similarly, please provide us with adequate milestones that are clearly tied to individual work and people-months for the next year.

- **Budget Information**. In our effort to ensure that our limited funds are put to the most efficient use, we want to determine if there is an overlap of efforts supported by DOE (through direct DOE funding to the national laboratories and other contractors) with those efforts being supported by the NCI (using the matching $250,000 that NCI and DOE contributes each year). Your budget submission for 1996 (as well as for 1995) only specifies general categories of expenses and does not provide us enough information to resolve this issue and to understand how you are spending the $500,000 of matching funds. We need a more detailed budget from you for 1996. In this context, we have incurred significant management costs for the Bel/Am Thyroid Study and would like to receive a copy of Everet Mincey's contract and a description of his general duties to ensure that there is no duplication of management efforts.

- **Management**. We completely agree with the view you expressed in your letter dated January 31, 1996, that we need to clearly define the responsibilities of the DOE and the NCI in managing this project. To achieve that goal, we would like to work with you and the Nuclear Regulatory Commission (NRC) to generate a list of the management responsibilities of the NCI and the management responsibilities of the DOE. It is particularly important to our office that DOE's responsibilities are clearly defined and accepted by the all the involved parties, because, as your know, **DOE is the agency legally accountable for this project**. To help us begin this process, please send us a draft list of NCI's responsibilities as you envision them. We also would appreciate receiving clarification on the role of Dr. David Becker, the Chairman of the U.S. Committee, and the rest of the scientific working group.

As you know, we have many similar concerns regarding the thyroid and leukemia studies in Ukraine. In fact, we have temporarily postponed our planned trip to Ukraine (scheduled for February 22, 1996) until some of these issues are resolved. Because we share your concern about moving both these projects along in a timely manner, we would appreciate receiving the requested information by March 1, 1996.

Finally, I appreciated receiving your letter dated January 31, 1996. Your letter helped us to clarify some of the issues that I have articulated in this letter. We look forward to working closely with you and the NRC on this project and we are anxious to keep our lines of communication open. In this regard, we have not received the information that Mr. Hawkins requested from you in his informal memorandum dated December 21, 1995 (copy enclosed).

Please contact me if you have any questions regarding the items requested at (301) 903-2105.

Sincerely,

Elaine K. Gallin, Ph.D.
Deputy Director
Office of International
Health Programs

Enclosure

cc w/enclosure:
Al Rabson, NCI
Faye Austen, NCI
Andre Bouville, NCI
James Taylor, NRC
Shlomo Yaniv, NRC
Lynn Anspaugh, LLNL

ATTACHMENT

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INTERNAL MILESTONES FOR NCI CHORNOBYL PROGRAM STAFF DURING FY 1997 OCTOBER-DECEMBER QUARTER AND BEYOND

Recent organizational changes introduced on the U.S. side, along with the opening of the implementation phase of all operations, make it necessary for NCI staff to develop interim plans for its activities, primarily for the first quarter of FY 97 and extending through calendar year 1997. We fully expect to stay flexible so as to be able to react to unexpected contingencies such as may occur in this operation, which is new to all parties. Accordingly, these milestones will be amended as necessary, pehaps monthly. We expect to develop more detailed quarterly schedules one month before the beginning of each quarter.

October 96	Contract concept for support services for the Chornobyl program to be reviewed by the Executive Committee, NCI
	Staff visit to Belarus to review progress during the past six months and assess readiness to initiate clinical operations
	Staff member and consultants to participate in the workshop on protocols for the study of cancer risk among Chornobyl liquidators at IARC, Lyon, France
	Official signing of the U.S.-Ukraine Agreement for Cooperation on implementation of the scientific protocol for the study of leukemia among clean-up workers in Ukraine
	Establish the American component of the Binational Advisory Group for thyroid cancer projects
	Establish contact with the VA Acquisition Center for procurement of equipment and supplies; initiate documentation for their assistance to the Chornobyl Projects
	Sign new Interagency Agreement with DOE
	Transfer of funds from DOE to NCI for the Chornobyl Projects
	Prepare and implement support contract with Moscow Institute of Biophysics for support to the Belarusan Thyroid Cancer Project
	Review new priority lists for purchase of equipment and supplies for thyroid projects in Ukraine and Belarus
	Draft RFP for support contract to Chornobyl Program

November 96	Approve milestones for Leukemia project
	Sign funding arrangement for local support to the leukemia project
	First meeting of the U.S.-French Steering Committee for Leukemia
	Arrange for the first meeting of the Binational Advisory Groups in Kyiv and Minsk
	Working teams visits to Ukraine and Belarus
	Two hematology candidates from Ukraine to train at NIH in preparation for their duties in the leukemia project
	BSA review of the support contract proposal prior to issuing the RFP, if necessary
	Review and approve equipment requests for leukemia project; initiate the procurement process
December 96	Publish the RFP for support contract to the Chornobyl Program
	Initiate operations in the leukemia project
	Two candidates from the leukemia project to train in U.S.: one in dosimetry, one in administrative computer technology
	Review available operations manuals, forms, questionnaires, etc. for all projects
1997	First meeting of the Binational Advisory Groups in Kyiv and Minsk
	Evaluate extension of Minsk operations to Gomel; develop relevant documentation for funding, equipment, supplies, local support etc.
	Review initial results of clinical procedures, including examinations, ultrasound, laboratory tests and cytology/pathology as appropariate
	Review operation of the DCC's
	Sign the support contract for the Chornobyl program
	Organize quarterly visits of specific working groups to all projects

1997 cont.	First annual program review
	Preparation of Annual Progress Report
	Preliminary review of the feasibility for Phase II of the Leukemia Project
	Continued quarterly meetings of the U.S.-French Steering Committee for Leukemia
	Review and renewal of IRB approvals
	Review quarterly project reports
	Develop milestones for subsequent quarters

Ihor J. Masnyk, PhD
U.S. Project Director
8 Oct 96

RADIATION EFFECTS BRANCH - DIVISION OF CANCER BIOLOGY

CHORNOBYL PROJECTS

MANAGEMENT PLAN

FY 1997

- Negotiate and implement an Interagency Agreement (IA) with DOE for continuation of the Chornobyl Projects, with complete management responsibility assigned to the NCI staff.
- Negotiate an IA with NRC for continued support for procuring equipment and supplies for the three Chornobyl projects.
- Develop a support contract to assist the NCI in the management of the three Chornobyl Projects: BelAm Thyroid Project
  UkrAm Thyroid Project
  UkrAm Leukemia Project.
- Negotiate and implement an IA with Veterans Affairs National Acquisition Center (VANAC) for procurement and delivery of equipment and supplies to these projects in Belarus and Ukraine.
- Begin placing orders for equipment and supplies for Ukraine and Belarus using the established IA with VANAC.
- Negotiate two tri-partite arrangements with the Science and Technology Center for Ukraine in Kyiv for handling the funds transfer for local support of the Ukrainian Projects to be implemented at the Institute of Endocrinology and Metabolism and at the Research Center for Radiation Medicine for the thyroid and leukemia studies, respectively.
- Arrange for timely transfer of funds for local support of the BelAm staff.
- Renew the approval of Institutional Review Board for the protocols used in the thyroid studies. Obtain approval for the Leukemia project.
- Develop a working relationship with the French colleagues at IPSN in regard to their participation in the leukemia project.

FY 1998

- Identify and establish the U.S. participants in the Binational Advisory Group for the thyroid projects in Ukraine and Belarus.
- Develop working relationship with staff personnel of the Agency for Reconstruction and Development of Ukraine to obtain relief from customs taxes

on goods delivered to the Ukrainian projects.

- Monitor work of three projects with the assistance of NCI staff, NCI consultants, and contract personnel provided under the contract with Columbia University.

- Develop procedures for the inventory of equipment provided to the three projects: develop a system for timely delivery of consumables required for the project.

- Train select candidates from Ukraine and Belarus in the U.S.

- Consider the possibility of an extension of the BelAm thyroid project to the Gomel Oblast in order to fulfill the requirements of the scientific protocol, with proper consideration of added financial requirements.

- Attend to the timely renewal if all IA. contracts and the IRB requirements

- Develop an arrangement with the institutions in Ukraine and Belarus to install an NCI representative(s) in residence to facilitate communication between study centers and NCI, to ensure quality control, recognize operational problems and assist in their resolution by their own and NCI resources.

- Continue collaboration with international groups by developing optimal methodologies for estimating dose to the thyroid and to the bone marrow and by collaborating in possible data exchange on patients examined in overlapping studies.

FY 1999

- Arrange for the first meetings of the Binational Advisory groups to review the thyroid projects in Ukraine and Belarus.

- Modify the two scientific protocols for the thyroid study on the basis of the early experience and the recommendations of the Binational Advisory Group.

- Prepare for possible inauguration of Phase II of the full leukemia project on liquidators and seek funds for interim period of decision-making for Phase II.

- Review thyroid screening cancer data for 1986-1996 with a view to reporting on the retrospective phase of the study in 2000.

- Attend to the renewal of the required contracts, agreements and approvals.

- Renegotiate the commitments for local support in light of expanding thyroid screening programs.

- Develop service and maintenance contracts for the equipment provided for the three projects.

- Maintain annual inventory accountability for the delivered equipment.

- Consider the possibility of limiting the annual visits to fewer trips annually for overall reviews of the progress, relying primarily on the on-site agents for orderly progress of the work.

- Maintain support of NCI resident representatives in Belarus and Ukraine.

- Review the results of Phase I of the leukemia project.

- Continue the training programs.

- Continue to monitor the progress of all three studies.

- Continue established collaboration with other international groups developing optimal methodologies for estimating dose to the thyroid and the bone marrow; establish new ties advantageous to the projects.

FY 2000

- Continue the established routines in regards to renewals of expiring documents, permits and agreements, provisions of local support funds, replacement of old equipment and acquisition of new equipment, along with timely service and maintenance operations.

- Hold second meeting of Binational Advisory Groups to evaluate progress, suggest and necessary changes in the research protocols for the thyroid projects, and consider whether the retrospective data on thyroid cancer are suitable for publication.

- Prepare preliminary report on the thyroid cancer data for 1986-1996 with a view to possible publication.

- Make final decision on Phase II of leukemia project; if Phase II is approved, re-write the protocol based on Phase I results, seek funds for implementation and establish Binational Advisory Group for leukemia project.

- Maintain support for NCI representatives in residence.

- Monitor progress of work on the thyroid projects.

- Continue the training program.

- Continue the efforts in international collaboration.

FY 2001

- Hold the third meeting of Binational Advisory Groups to evaluate progress. consider changes in research protocol, in operational procedures etc.

- Maintain support for NCI resident representatives.

- Renegotiate the support contract.

- Monitor work on projects in the field through visits by NCI personnel, NCI consultants . support contract personnel and the NCI representatives in residence.

- Submit for publication first report of retrospective data on thyroid cancer in the period 1986-1996 for Belarus or Ukraine or both.

- Continue continuation of collaboration with international groups.

ANNEX II

Tasks and Milestones

Preamble:

1. Estimates of man-month requirements are intended for administrative purposes only and are independent of funding levels.

2. Milestones may be changed during the course of the study upon mutual agreement of both parties.

3. Quarterly reports will reflect the progress of each milestone during the period of its implementation, with a final report due upon completion of the milestone.

Task I. SAMPLING

Milestone 1. Investigate Registry.

Investigate the Chernobyl Registry. The task is to determine whether the Registry will be an appropriate basis for selecting the cohort. Study the possibility of obtaining necessary individual data for each member of cohort. Study all information stored in data base of Chernobyl Registry.

Deliverable:	Narrative report.
Report due:	At the end of the first quarter.
Period:	Months 1-3.
Man-months:	5.0

Responsible Individual: Dr. B. Ledoshchuk.

Milestone 2. Obtain Registry Tabulations.

These are the tabulations of characteristics of clean-up workers on the basis of which decisions would be made to select the cohort and to choose the information to be taken off for each potential subject.

Deliverable:	Narrative report.
Report due:	At the end of the first quarter.
Period:	Months 1-3.
Man-months:	6.5

Responsible Individual: Dr. B. Ledoshchuk

Milestone 3. Verify Record Linkage.

The effort involves investigating the record-linkage procedures in place at the Chernobyl Registry and elsewhere, and determining their adequacy for the operation of the proposed study.

Deliverable: Narrative report.
Report due: At the end of the first quarter.
Period: Months 1-3.
Man-months: 6.0

Responsible Individual: Dr. B. Ledoshchuk.

Milestone 4. Assemble Cohort.

On the basis of the previous investigations, copy the record elements of the registry file for the subjects eligible according to the protocol and transfer this new file to the Research Center for Radiation Medicine. Select the sub-cohort of 1,000 to represent the cohort.

Deliverable: Narrative report.
Report due: At the end of the first and second quarters.
Period: Months 2-6.
Man-months: 12.5

Responsible Individual: Dr. B. Ledoshchuk.

Milestone 5. Select "Lost to Follow Up."

To find "Lost to follow up" among cohort members resident in one oblast under study. A representative sample of 50 persons will be chosen.

Deliverable: Narrative report.
Report Due: At the end of the second quarter.
Period: Months 4-6.
Man-months: 7.0

Responsible Individual: Dr. B. Ledoschuk

Milestone 6. Complete Search for "Lost to Follow Up."

Tracing of "Lost to follow up." The task is to find the "Lost to follow up" and determine the best method of minimizing "Lost to follow up" in Phase II.

Deliverable: Narrative report.

Report Due: At the end of first and second quarter.
Period: Months 4-6.
Man-months: 18.0

Responsible Individual Dr. B. Ledoschuk

Milestone 7. Identify High-Dose Subcohort.

The task is to identify subjects having doses greater than 0.5 Gy.

Deliverable: Narrative report.
Report due: At the end of the first and second quarters.
Period: Months 1-6.
Man-months: 13.0
Responsible Individual: Dr. V. Klimenko.

Task II. Dosimetry

Milestone 8. Investigate Dosimetry Sources and Needs.

Contact will be established with potential holders of primary dosimetric information (Chornobyl NPP, "Pripjat" Association, "Complex", Department of Construction-605, etc.). Archives of organizations which had participated in clean-up as well as databases of acting dosimetric departments will be analyzed. On the basis of the analysis of the available information, a conclusion on the usefulness of the above-mentioned data for dosimetric support of the project will be made.

Deliverables: Narrative report.
Report due: At the end of the first and second quarters.
Period: Months 1-6.
Man-months: 9.0

Responsible Individual: Dr. V. Chumak.

Milestone 9. Study Tasks of Clean-up Workers.

An analysis and systematization of information about the kinds, localization, periods and purpose of activities carried out during the clean-up will be performed. This analysis will require the participation of a qualified dosimetrist who is familiar with the history of clean-up and characteristics of working sites. This work will be based on official data as well as on interviews with persons who were responsible for the organization of the work at different stages of the clean-up. Working conditions and environments at the time of clean-up will be categorized. The aim of this categorization is two-fold: possible assignment of dose estimates by a group method and evaluation of the usefulness of the acquired information for the design of questionnaire.

Deliverables: Narrative report.
Report due: At the end of the first, second, third and fourth quarters.
Period: Months 1-12.
Man-months: 15.0

Responsible Individual: Dr. V. Chumak.

Milestone 10. Do 20 Representative Workers.

Filling out the route list (in the questionnaire) and reconstruction of individual dose will be performed for 20 reasonably representative liquidators. Doses will be reconstructed according to methods developed by RCRM, IBP (Moscow) and Chernobyl NPP and will include the following elements: filling out the questionnaire and preparation of the route list with participation of an expert who is extremely familiar with the history of clean-up conditions at the working sites; analysis of the data included into the route list for evaluation of likelihood of the reported data; analysis of the dose by three independent experts and derivation of one dose estimate per subject.

Deliverable: Narrative report
Report Due: At the end of the second, third, fourth, fifth and sixth quarters.
Period: Months 6-18.
Man-months: 14.0

Responsible Individual: Dr. V. Chumak

Milestone 11. Inventory Questionnaire Data.

The major data arrays of this kind are the database of ChNPP, materials of the International Consortium and an archive of the department of dosimetry of CRM. Inspection of databases containing the results of survey and dose estimation will be required. The result of the work will be a conclusion about the current status of acquiring exposure information for dosimetric support of the Project.

Deliverables: Narrative report
Report due: At the end of the second and third quarters.
Period: Months 2-7.
Man-months: 6.0

Responsible Individual: Dr. V. Chumak.

Milestone 12. Estimate Need for New Questionnaire Effort.

Determine whether an available questionnaire is adequate for obtaining epidemiological and dosimetric information or a new one must be designed.

Deliverable: Narrative report.
Report Due: At the end of each quarter
Period: Months 1-18.
Man-months: 5.0

Responsible Individual: Dr. B. Ledoschuk

Milestone 13. Investigate Tooth Sampling.

A central bank for storage of teeth extracted according to medical indications will be established. Mechanisms of acquisition and transmission of teeth to the central bank will be investigated.

Deliverables: Narrative report.
Report due: At the end of each quarter.
Period: Months 1-18.
Man-months: 12.0

Responsible Individual: Dr. V. Chumak.

Milestone 14. Establish EPR Labs: Test Teeth.

This task includes the whole cycle of activities and methodological research associated with the installation of the modern EPR-dosimetric facility. Such activities include: the purchase and installation of the modern equipment, the adaptation of the currently used technique to the new instrumentation, the development of the high performance routine EPR-dosimetric technique, and, finally, the beginning of the routine reconstruction of individual doses for participants.

Deliverables: Narrative report.
Report due: At the end of third, fourth, fifth and sixth quarters.
Period: Months 3-18.
Man-months: 62.0

Responsible Individual: Dr. V. Chumak.

Milestone 15. Establish Biodosimetry.

The task implies installation of FISHT method into the practice of the cytogenetic lab.

To achieve this goal the following activities will be undertaken: receiving, mounting and mastering the equipment for FISHT method.

Deliverables: Narrative report.
Report due: At the end of the first and second quarters.
Period: Months 1-6.
Man-months: 8.0

Responsible Individual: Dr. M. Pilinskaya

Milestone 16. Do Biological Tests on Bloods.

The task is to draw blood and perform FISHT analysis on at least 30 clean-up workers with known doses.

Deliverables: Narrative report.
Report Due: At the end of each quarter.
Period: Months 3-18.
Man-Months: 62.0

Responsible Individuals: Dr. M. Pilinskaya and Dr. V. Klimenko

Milestone 17. Validity of Biological Dosimetry.

Cytogenetic observations will be made on 10 to 15 patients with leukemia and lymphoma in order to assess the influence of pathology on the doses obtained by biodosimetry.

Deliverables: Narrative report.
Report Due: At the end of each quarter.
Period: Months 6-17.
Man-Months: 3.0

Responsible Individual: Dr. M. Pilinskaya

Milestone 18. Accumulate Tissues for Banks.

Blood, bone marrow samples, lymph-node tissues, bone biopsies, teeth from patients with leukemias will be accumulated and banked under suitable temperature conditions.

Deliverables: Narrative report.
Report Due: At the end of the second and next quarter.
Period: Months 6-17.

Man-Months: 30.0

Responsible Individuals: Dr. V. Chumak
Dr. V. Klimenko

Milestone 19. Compare Various Dose Estimates.

To compare biological and physical doses from different sources.

Deliverables: Narrative report.
Report Due: At the end of the sixth quarter.
Period: Months 15-18.
Man-Months: 6.0

Responsible Individual: Dr. V. Chumak

Task III. Leukemia and Lymphoma

Milestone 20. Update 1987-1996 Leukemias and Lymphomas

Update leukemia, and lymphoma in one oblast under study from 1987 to 1996 among the members of cohort.

Deliverables: Narrative report.
Report Due: At the end of the second, third and fourth quarters.
Period: Months 4-12.
Man-Months: 32.0

Responsible Individuals: Dr. V. Klimenko
Dr. B. Ledoschuk

Milestone 21. Link Leukemias and Lymphomas to Registry.

Link leukemia and lymphoma among inhabitants of one oblast under study to Registry. Link this information with Chernobyl Registry to identify the cases in the cohort study .

Deliverables: Narrative report.
Report due: At the end of the fifth quarter.
Period: Months 13-15.
Man-months: 12.0

Responsible Individual: Dr. B. Ledoschuk

Milestone 22. Diagnostic Review of 50 Leukemia and 20 Lymphoma Cases.

Analyze 50 representative leukemia and 20 representative lymphoma cases, together with American scientists, including peripheral blood, bone marrow, lymph-node smears, bone biopsies and medical records.

Deliverables:	Narrative report.
Report due:	At the end of the fourth and fifth quarters.
Period:	Months 10-15.
Man-months:	10.0

Responsible Individual: Dr. V. Klimenko

Milestone 23. Learn Ascertainment of Other Hematological Diseases.

To study the possibilities of ascertaining other hematological diseases. Analysis of medical documentation of blood and bone marrow smears.

Deliverables:	Narrative report.
Report due:	At the end of the second, third and fourth quarters.
Period:	Months 2-12.
Man-months:	22.0

Responsible Individual: Dr. V. Klimenko

Milestone 24. Meeting with Hematologists, Oncologists and Pathologists.

Meeting with hematologists of all oblasts for the explanation of goals of the project and also to obtain their cooperation.

Deliverables:	Narrative report.
Report due:	Report at the end of the first quarter.
Period:	Month 1.
Man-months:	6.0

Responsible Individual: Dr. V. Klimenko

Milestone 25. Validate Exposure Check-off.

Determine whether official liquidator status markers exist in emergency medical forms used in Ukrainian medical documentation.

Deliverables:	Narrative report.
Report due:	Report at the end of the fifth quarter.
Period:	Month 13-15.
Man-months:	5.0

Responsible Individual: Dr. B. Ledoschuk

Task IV. Molecular Biology

Milestone 26. Bleed High-dose Subjects.

Getting blood samples for hematological analyses from high-dose persons and processing them for long-term storage.

Deliverables:	Narrative report.
Report due:	At the end of each quarter.
Period:	Months 1-18.
Man-months:	8.0

Responsible Individual: Dr. V. Klimenko

Milestone 27. Obtain and Process Blood and Bone Marrow Samples Before Treatment.

To collect and process blood samples and bone marrow samples from new patients with leukemia and other hematological diseases before treatment.

Deliverables:	Narrative report.
Report due:	At the end of each quarter.
Period:	Months 1-18.
Man-months:	16.0

Responsible Individual: Dr. V. Klimenko

Milestone 28. Evaluate Training and Equipment Needs.

To evaluate needs in training and for equipment for molecular study.

Deliverables:	Narrative report.
Report due:	At the end of the sixth quarter.
Period:	Months 16-18.
Man-months:	3.0

Responsible Individual: Dr. V. Klimenko

Milestone 29. Explore High-dose Sample Size.

The task is to determine whether a sufficient number of high-dose subjects can be identified to expect useful scientific results to be obtained in studies of pathogenesis and molecular biology.

Deliverables:	Narrative report.
Report due:	At the end of first and other quarters.
Period:	Months 1-15.
Man-months:	12.0

Responsible Individuals: Dr. V. Klimenko
Dr. B. Ledoschuk

Task V.

Milestone 30. Identify, Trace, Interview 40 Persons; Bleed 20.

Identify, trace, interview 40 members of the cohort living in one oblast under study and get blood samples from 20 persons at the time of routine polyclinic examination. At least 20 members would be sought directly (at home, at work, etc.) for interview only.

Deliverables:	Narrative report.
Report due:	At the end of second and other quarters.
Period:	Months 4-15.
Man-months:	40.0

Responsible Individuals: Dr. V. Klimenko
Dr. B. Ledoschuk

Task VI. Training

Milestone 31. Determine Training Needs for Phase II.

Deliverable:	Proposals for training.
Report due:	At the end of the sixth quarter.
Period:	Months 16-18.
Man-months:	3.0

Responsible Individual: Dr. O. Piatak

Milestone 32. Evaluate Organizational Patterns, Phase II.

Deliverable:	Draft manuscript.
Report due:	At the end of the sixth quarter.
Period:	Months 16-18.
Man-months:	3.0

Responsible Individual: Dr. O. Piatak

Milestone 33. Assemble Advisory Group.

Deliverable:	Proposals.
Report due:	At the end of the sixth quarter.
Period:	Months 16-18.
Man-months:	3.0

Responsible Individual: Dr. O. Piatak

Task VII. Evaluation.

Milestone 34. Plan Protocol for Phase II--Budget, Design.

Deliverable:	Draft manuscript.
Report due:	At the end of the fifth and sixth quarters.
Period:	Months 16-18.
Man-months:	16.0

Responsible Individual: Dr. A. Romanenko

General Director of RCRM A. Romanenko

DRAFT

12 May. 1998

Consolidated Summary of Protocol Tasks for Leukemia Study

The following summary is intended re-state the June. 1997. draft prepared by Dr Pyatak. with up-dates based on discussions and correspondence later in the year. especially:

10/20/97 letter from Dr Finch to Dr Romanenko
11/14/97 letter from Dr Beebe to Dr Romanenko
11/21 letter from Dr. Romanenko to Dr Wachholz
12/12/97 letter from Dr Finch to Dr Romanenko

The term "milestone" is equivalent to "task" in the research protocol. sections 5.0-5.2.9. but "task is used here to avoid confusion with the administrative reporting of progress on a quarterly basis. Numbers in parenthesis are those of the relevant sections of the protocol. as in Table 5.2.9 there. Underlined items have not previously been specifically listed and the statements here are based on the indicated paragraphs of the research protocol. They require special attention in reviewing this draft. This summary does not contain all the subtasks that may have been visualized or defined for the various milestones: such information is. however. provided for milestones 4. 6. 21. 24. 25.an 30 in Dr Pyatak's 6/97 document. and for milestones 22. 23. 24. 27. and 30 in Dr Finch's letter of 10/20/97 to Dr Romanenko.

Task 1. Investigate Registry (5.2.1.1)

1) Develop a conceptual model of the State Registry of Ukraine (SRU) with a description of the items of information needed for the database.

2) Determine the items of information in the individual files that will be selected for each member of the cohort (and subcohort) in the formation of the cohort (and subcohort) database

3) Explore the feasibility of the transfer of data from the Chernobyl Registry to the database for the project

Task 2. Obtain Registry Tabulations (5.2.1.1)

1) Obtain tabulations characterizing the participants in the liquidation of the effects of the Chernobyl accident: of particular interest are tabulations of age. sex. year of service. any recorded dose. last known residence. identifiers. and frequency of follow-up examinations

Task 3. Verify Record Linkage (5.2.1.1)

1) Obtain descriptions of any existing procedures for linking the Registry with other files

Task 4. Begin to Assemble Cohort (5.2.1.2)

1) Begin to create the cohort file consisting of men who participated in the accident work in 1986-1990. living at the time of registration in 6 areas: Dnipropetrovsk. Donetsk. Kharkiv. Sumy. Kiev oblasts and Kiev City.

(The variables to be taken for each person from the Registry will have been decided in Milestone 1)

3) The newly created file will be placed on the server of the Center for Information Technology and State Registry of the Ukrainian Ministry of Health and on that of the Research Center for Radiation Medicine, Ukrainian Academy of Medical Sciences

4) A representative subcohort of 1.000 subjects will be formed from the full cohort according to specifications to be provided

Task 5. Select "Lost to Follow-up" (5.2.1.3)

1) "Lost to Follow-up" will be defined as men for whom no information has been entered in the State Registry for 3 or more years.

2) 20 such men who entered the Registry through the Dniepropetrovsk Oblast facilities will be chosen at random from those eligible under the above definition

Task 6. Search for "Lost to Follow-up" (5.2.1.3)

1) Request latest address from dispensary or polyclinic where last seen

2) Direct-mail inquiry to clean-up worker at latest address asking why he has not been in for an examination lately

3) Consult other resources for men who do not reply or cannot be found

Task 7. Identify High-Dose Sample (5.2.1.4)

1) Identify the files that contain dose information

2) Select men with recorded or estimated doses of 0.5 or more Gy or Sv without regard to geographic restrictions

3) Create a separate file; some may be duplicated in the cohort

Task 8. Investigate Dosimetry Sources and Needs (5.2.2.1)

1) Assemble available information at the level of raw data

2) Review information available on various physical methods of estimating bone marrow dose

3) Determine what additional efforts would be needed to provide physical dose estimates (by environmental dose reconstruction and by ESR)

(N.B. Is there any description of task 8 other than in the long statement on dosimetry provided by Dr Pyatak in June, 1997?)

Task 9. Study Tasks of Cleanup Workers (5.2.2.1)

1) Collect and analyze available information on type of work, working environment, working conditions, date of exposure, and duration of exposure

Task 10. Make Physical Dose Estimates for 20 Workers (5.2.2.1)

1) For a representative sample of 20 workers, experiment with various methods of physical dose reconstruction

Task 11. Inventory Questionnaire Data (5.2.2.1)

(This task was superseded by the decision to collaborate with the WHO investigators of cleanup workers in BY and the RF in the development of a common instrument)

Task 12. Estimate Need for New Questionnaire Effort (5.2.2.1)

(This task also was accomplished by the decision to collaborate with the WHO team)

Task 13. Investigate Tooth Sampling (5.2.2.1)
1) The sampling situation will be investigated with a view to determining how best to obtain tooth enamel on members of the subcohort and on cases of leukemia and lymphoma

Task 14. Establish EPR Dosimetry Lab (5.2.2.1)
1) Strengthen existing facilities with necessary equipment and supplies
2) Continue methodologic research, including exchange of samples with reference laboratories

Task 15. Establish Biodosimetry Lab (5.2.2.2)
1) Strengthen existing facilities with necessary equipment and supplies
2) Perform necessary training

Task 16. Do Biological Tests on Bloods. (5.2.2.2)
1) In support of the task of comparing the various methods of dose estimation, for a well-chosen sample of 60 workers with EPR and environmentally reconstructed dose estimates, independent dose estimates will be made by the FISH method

Task 17. Validity of Biological Dosimetry (5.222)
1) Blood samples obtained prior to therapy for leukemia and lymphoma will be investigated by cytogenetic methods, including FISH, to determine whether cytogenetic dose estimation is compromised by the presence of disease

Task 18. Accumulate Tissues for Banks (5.2.2.2)
1) Study possibilities for accumulating tissue and begin creating a tissue bank for patients with leukemia and lymphoma
2) Evaluate existing procedures and equipment for archiving teeth and derivative material

Task 19. Compare Various Dose Estimates (5.2.2.2)
1) Prepare a formal design for comparing doses obtained independently by environmental dose reconstruction, EPR, and FISH for 60 workers
2) Locate and bleed the 60 workers for FISH determinations (Cf Task 16)
3) Analyze the results statistically in pairs of methods and, to the extent possible with the numbers available, for all three methods simultaneously

Task 20. Update 1987-1997 Leukemia and Lymphomas (5.2.3.2)
1) Search for leukemia and lymphoma cases among men aged 20-60 in the records of the Hematological Department of the Dnipropetrovsk Oblast Hospital, the oblast oncologic dispensary, and the dispensary branch for monitoring Chernobyl victims, note any indication of Chernobyl status, and compare the resulting list with the State Chernobyl Registry

Task 21. Link Leukemias/Lymphomas to Registry (5.2.3.2)
1) Search the State Registry for the cases of leukemia and lymphoma found in Task 20
2) Evaluate the State Chernobyl Registry as the primary source of information on leukemia and lymphoma in the study cohort for the period 1987-1997

Task 22. Review Diagnoses of 50 Leukemias and 50 Lymphomas (5.2.3.3)

1) From each of the 5 participating oblasts and Kiev City the clinical material (clinical record and any and all pertinent hematology slides of peripheral blood and bone marrow) will be assembled for representative cases of chronic myelogenous leukemia (1 or more). acute leukemia (3 or more). leukemia-related disorders. i.e.. myelodysplasia. myelofibrosis. polycythemia vera. thrombocythemia. etc.. (2 or more). non-Hodgkin's lymphoma (3 or more). Hodgkin's disease (2 or more). and multiple myeloma (1 or more) diagnosed in the period 1987-1997

2) Selection will be made by random numbers by the epidemiology staff from lists provided by each oblast supporting clinical material will be assembled. no matter how incomplete

3) A US (and French)- Ukrainian team of experts will judge the clinical and histologic material for adequacy. propose standard diagnostic classifications appropriate for Phase II. and recommend corrective measures. diagnostic guidelines. and other procedures suitable for a hematology manual

Task 23. Learn Ascertainment. Other Diseases (5.2.3.4)

1) The records of the hematology departments of the Dnipropetrovsk Oblast will be searched for leukemia-related diagnoses (i.e.. myelodysplasia. polycythemia vera. thrombocythemia. aplastic or hypoplastic anemia. and myelofibrosis). and any indication of Chernobyl status will be noted

2) The resulting list will be searched in the Chernobyl Registry for the presence of these diagnoses in that file

3) A decision will be made as to the feasibility of studying these diagnoses in the cohort for the period 1987-1997

Task 24. Meeting with Hematologists. Oncologists. and Pathologists (5.2.3.5 & 6)

1) Early in the project representatives of the Research Center of Radiation Medicine will hold a one-day orientation meeting with 1-2 key hematologists from each of the 6 study areas to describe the plans for Phase I and Phase II

2) Before interviews begin and blood is drawn. representatives of the Research Center of Radiation Medicine. together with US and French colleagues will meet with the hematologists and other personnel in Dniepropetrovsk to provide detailed information about such study procedures as interviewing. drawing. processing. and shipping bloods. diagnostic criteria. and informed consent.

Task 25. Validate Exposure Check-off (5.2.3.7)

This task may have been incorporated into tasks 20 and 23

Task 26. Bleed and Process High-Dose Subjects (5.2.4.1)

This task has been incorporated in task 30

Task 27. Obtain and Process Pre-Treatment Blood. Marrow (5.2.4.2)

1) Pre-treatment blood and bone marrow from at least 3 adult patients in Dnipropetrovsk with leukemia or a related disorder (male or female) and one with lymphoma (with fresh tissue) will be processed in accordance with Appendix 3 of the protocol

2) Lacking adequate material from Dniepropetrovsk any deficit may be filled by material from patients in Kiev

Task 28. Evaluate Training and Equipment Needs (for Molecular Biology). Phase II (5.2.4)
1) From the experience in Phase I specific plans will be made for any necessary training and for the procurement of equipment for Phase II

Task 29. Explore High-Dose Sample Size (5.2.4.2)
1) From the information obtained in meeting Task 7 a determination will be made as to the adequacy of the size of the sample in light of the objectives of the protocol

Task 30. Identify. Trace, and Interview 40. Bleed 20 (5.2.5. 5.2.2.2)
1) Select two representative samples of about 20 workers each in the Dniepropetrovsk Oblast from the State Registry
2) One sample is to be located and interviewed to obtain information needed for dose estimation and to obtain a brief medical history
3) The other sample is to be interviewed and bled at the time of a polyclinic examination
4) The general and medical information obtained is to be compared with information in the State Chernobyl Registry
5) The bloods are to be processed in accordance with Appendix 3 of the protocol and shipped to Kiev

Task 31. Determine Training Needs for Phase II (5.2.6)
1) From the experience in Phase I any training needs, whether in Ukraine or in the US will be determined

Task 32. Revaluate Organizational Patterns for Phase II (5.2.7)
1) From the experience in Phase I and the ideas in the research protocol a determination will be made as to the identity of the cooperating organizations (4 were planned for Phase I), the organization of the project staff in relation to the work of the project, and the relationship between the project and the various organizations in the field from which information will be obtained

Task 33. Assemble Advisory Group, Phase II (5.2.7)
1) An advisory mechanism will be visualized

Task 34. Plan Protocol and Budget for Phase II (5.3)
1) Revise the present protocol on the basis of the reports on the individual milestones (tasks in the protocol), once feasibility has been demonstrated and scientific yield reasonably assured
2) The revision should take into account research objectives, personnel requirements, equipment and supplies, and budget

***

(N.B. Tasks 31-34 are the joint responsibility of the US (and French) sponsors and the Ukrainian sponsors)

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July 19, 1998

To: **Bruce W. Wacholz, Ph.D.**
Chief, Radiation Effects Branch
National Institute of Health, National Cancer Institute,
Bethesda, Maryland, 20892 USA

Subject: In reply to draft paper "Consolidated summary of Protocol Tasks in Leukemia study" (Dr.Beebe and Dr.Masnyk, May 12, 1998)

Cc: **Ihor G. Masnyk, M.D.r**
Cc: **Gilbert W. Beebe, Ph.D.**
Cc: **Stuart C. Finch, Ph.D.**

Dear Dr. Wacholz,

Our group and I personally are greatly impressed by the work, which was done by our US colleagues. We are grateful to you for these efforts and realize that all the suggestions are aimed to make the finish of Phase 1 and beginning of Phase 2 successful.

We have thoroughly re-checked all the tasks in our groups and two general meetings were performed to discuss the items. We agree with the general idea and most of the suggestions. Here we present our comments on some of the specific tasks, which have to be clarified more precisely.

The style of project analysis in Draft paper seems to be very useful for analysis so we have preserved it in our reply. Response to newly defined items is underlined as in the primary document.

Task 1- Investigate registry - 5.2.1.1

1-2) Items 1 and 2 are neglecting the work activities, which have been performed during the first and the second quarter. We have encountered these suggestions in the Quarter 2-report revision.

3)Item 3 was not clarified as a separate entity before and was considered to be a part of the data transfer from Chernobyl registry to project database. We will perform the transfer after the computer net installation and cohort file formation.

Task 2- Obtain registry tabulations- 5.2.1.1

1)The task was performed during Quarter 1. Identifiers that are used in the Registry have been enumerated in the Quarter report 1 at the Regisry individual file variables list. Last known residence and the date of last follow-up examination are the parts of individual file. Quantity of persons who didn't undergo annual follow-up and distribution due to the time of data absence were presented in the Quarter 2 report (task 5 , table 2).

Task 3- Verify records linkage- 5.2.1.1

1)The task was performed during Quarter 1 due to the coordinated plan.

Task 4- Begin to assemble Cohort- 5.2.1.2

1,3) The items were coordinated previously and didn't cause disagreements.

4) The specifications of representative cohort formation would be the subject of additional discussion of our epidemiological group with the US side. At the present stage subcohort formation is planned as a sample of 1000 persons stratified by age and residence at the moment of registration.

Task 5- Select "Lost to follow-up"- 5.2.1.3

1-2) The task was coordinated previously and performed due to Quarter 2 plan.

Task 6- Search for "Lost to follow-up"- 5.2.1.3

1-2) These suggestions are used already during the project elaboration.

3) All the available methods of "lost to follow-up" persons localization is planned to be used including the informational search in medical hospitals which are responsible for the follow-up, Registry oblast and regional facilities, Passport offices of the Ministry of Internal Affairs, individual post contacts etc.

Task 7- Identify High-Dose Sample- 5.2.1.4

1) A work on identifying the files that contain dose information will be continued
2) Persons with doses of 0.5 Gy or higher will be included without regard to geographical residence.
3) A separate file is created for the persons with doses of 0.5 Gy and more.

Task 8- Investigate dosimetry sources and needs- 5.2.2.1

1) Assembling the available information at the level of raw data is not real. It's very expensive and not simple at the organizational level. At the short meeting of Dr. Chumak with Dr. Bouville on May 18-20, 1998 it was suggested to change the item "assemble available information" for "identify the available information". This task was fulfilled during the Quarter 2 and the corresponding table was included to the report.

2-3) There aren't objections to perform this work despite these items haven't been included to the Protocol previously. Formally the Task 8 is finished in Quarter 2, so the items have to be formulated as a separate task or inluded to the other tasks.

Task 9- Study tasks of cleanup workers - 5.2.2.1

1) We agree to include these items

Task 10- Make physical dose estimates for 20 workers - 5.2.2.1

1) We agree to include these items but it's not clear for us what various methods of physical dose reconstruction are planned to include. Previously the task was based on one method of analytical dose reconstruction.

Task 11 -12- Inventory Questionnaire data - 5.2.2.1
Estimate need for new questionnaire effort - 5.2.2.1

We haven't objections provided that these tasks will reflect our participence in Dosimetric work group (Cardis, Kriuchkov e.a.) We have made the significant amount of work in this direction including the participance in Questionnaire preparation, interviewers training and are ready to participate in future in practical questionnaire employment, mutual research with Kriuchkov on the "soft estimations" assay. Clear instructions are in need in this aspect how to change this Project task and how to prepare quarter reports.

Task 13 Investigate tooth sampling - 5.2.2.1

1) We haven't objections.

Task 14 Establish EPR dosimetry - 5.2.2.1

1-2) We haven't objections.

Task 15 Establish Biodosimetry lab - 5.2.2.2

1-2) We haven't objections.

Task 16 Do biological tests on bloods - 5.2.2.2

1) This task is performed now despite not all the materials are provided. Due to the Project 50 workers have to be investigated by EPR, FISH and analytical dose reconstruction and all the reagents were purchased for this quantity of samples. If the figures are changed corrections have to be made.

Task 17 Validity of biological dosimetry - 5.2.2.2

1) The question of disease (leukemia or lymphoma) influence on the results of cytogenetic analysis is very important to our opinion too. so the corrections have to be made and as in the task 16 sufficient reagent quantity is in need. Blood samples from the Leukemia and lymphoma patients will be transferred to biological dosimetry unit in the needed amount.

Task 18 Accumulate tissues for Banks- 5.2.2.2

1) The study is in the progress
2) There aren't objections from our side.

Task 19 Compare various dose estimates- 5.2.2.2

1-3) There aren't objections from our side. The number of samples and people under the investigation needs to be clarified more precisely (50 or 60) as in task 16.

Task 20 Update 1987-1997 Leukemia and Lymphomas - 5.2.3.2

1) Search of Leukemia/lymphoma cases is performed in the records of all the mentioned sources with indications of Chernobyl status. After that search of ill patients is performed in the Registry and check of the Registry primary data about the patients.

1) Leukemia/lymphoma (and related pathology) diagnoses established in 1987-97 sampling is performed among men from Dnipropetrovsk oblast born in 1926-1966.

2) Obtained data linkage with the Registry is performed to estimate the effectiveness of such a method of case identification in the cohort and Registry cases information completeness. Additional methods could be used to evaluate the Registry as a primary source after discussion with US side.

Task 22 Review diagnoses of 50 leukemias and 50 lymphomas - 5.2.3.3

1) Clinical material will be assembled from 5 oblasts and Kiev as proposed.

2) Epidemiological group will perform the needed selection by random numbers.

3) Experts team will re-evaluate the clinical and histologic data and propose diagnostic classifications for Phase 2.

Task 23 Learn ascertainment, other diseases - 5.2.3.4

1-3) Leukemia related pathology will be searched in Hematology departments and registry, a decision about the feasibility of such pathology will be made.

Task 24 Meeting with hematologists, oncologists and pathologists - 5.2.3.5 & 5.2.3.6

1) The time schedule of orientation meetings in all the regions is elaborated and the Research Center of Radiation Medicine teams will begin from the end of July

2) Meeting in Dnipropetrovsk was held during US/French team visit in May, 1998.

Task 25 Validate exposure check-off - 5.2.3.7

We have no objections.

Task 26 Bleed and Process High-Dose subjects - 5.2.4.1

We have no objections.

Task 27 Obtain and process pre-treatment blood and bone marrow - 5.2.4.2

1) We have no objections to include male and female as it's proposed.

2) Possible lack of material will be filled by Kiev patients' material.

Task 28 Evaluate training and equipment needs (for molecular biology), phase 2- 5.2.4

1) We agree with the need of specific plan elaboration and consider for the aid from US partners in this aspect

Task 29 Explore high dose sample size- 5.2.4.2

1) A sample is formed now on the base of individual files, which are collected in Research Center of Radiation Medicine. Other sources will be explored and the adequacy of the sample as well.

1) Two samples of 20 workers each from Dnipropetrovsk oblast will be selected from the registry as proposed.

2) First sample fwill be located and interviewed as proposed.

3-5) Second sample will be interviewed and blood will be obtained, tranferred to Kiev and analyzed

4) Comparison of general and medical information will be made with the Chernobyl registry

Task 31 Determine training needs for Phase 2 - 5.2.6

1) Training needs will be estimated and training plan will be elaborated. Due to the agreement training in USA if needed will be asked by the project director from the Research Center of Radiation Medicine

Task 32 Reevaluate organizational patterns for Phase 2 -5.2.7

1) Cooperation partners and organizations will be determined and staff organization as well on the experience of Phase 1 and the estimated information needs.

Task 33 Assemble advisory group, phase 2 -5.2.7

1) Advisory mechanism will be clarified on the basis of mutual discussion and needs of the Project.

Task 34 Plan Protocol and Budget for Phase 2-5.3

1) Revision of Protocol and Reports will be started to meet the Phase 2 from the second half of Phase 1 (Quarter 4)

2) Research objectives revision will be discussed with US side, personnel requirements, needed equipment and supplies list will be prepared by Ukrainian staff and mutually discussed to plan the budget. US/French and Ukrainian sponsors will be responsible for planning of Phase 2.

Sincerely yours,

Anatoly Ye. Romanenko, M.D.,
Academician, Director,
Research Center for Radiation Medicine

SUMMARY

	1996	1997	1998	1999	2000	TOTAL
Belarus Thyroid Study	556,000	535,200	759,200	945,600	1,145,600	3,941,600
Ukraine Thyroid Study	990,000	1,104,000	1,123,000	1,080,600	1,106,200	5,403,800
Ukraine Leukemia Study	518,600	242,000				760,000
TOTAL	2,064,600	1,881,200	1,882,200	2,026,200	2,251,800	10,106,000
Contributions						
DOE	1,837,600	1,717,700	1,785,700	1,939,700	2,164,800	9,445,500
NCI	227,000	163,500	96,500	86,500	87,000	660,500
NCI Personnel*	495,000	508,225	520,930	533,952	547,299	2,606,222

*Total contribution to all projects
Assumes an average of $200 per man-month

BELARUS THYROID CANCER STUDY.

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	300,000	300,000	500,000	700,000	900,000	2,700,000
Local Assistance						
MINSK*	79,000	102,200	122,200	118,600	118,600	540,600
MOSCOW	30,000	35,000	40,000	40,000	40,000	185,000
Support	147,000	98,000	97,000	87,000	87,000	516,000
TOTAL	556,000	535,200	759,200	945,600	1,145,600	3,941,000
Contribution						
DOE	482,500	486,200	710,700	902,100	1,102,100	3,683,600
NCI	73,500	49,000	48,500	43,500	43,500	258,000
NCI Personnel**						

*Assumes an average of $200 per man-month

**Total contribution to all projects listed on summary page

Manpower Requirements

Task	1996	1997	1998	1999	2000	TOTAL
Belarus Thyroid						
Manage and administer project	63	63	63	63	63	315
Establish cohort	63	63	63	40	40	269
Arrange appearance of cohort	45	45	45	45	45	225
Perform clinical evaluations	105	210	300	300	300	1,215
Perform diagnostic confirmation	9	20	30	30	30	119
Plan data flow + write software	30	30	30	40	40	170
Reconstruct thyroid doses	30	30	30	25	25	140
TOTAL	345	461	561	543	543	2,453
X $200	69,000	92,200	112,200	108,600	108,600	490,600
Plus 10K Administration	79,000	102,200	122,200	118,600	118,600	540,600

UKRAINE THYROID CANCER STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	750,000	850,000	850,000	850,000	850,000	4,150,000
Local assistance*	108,000	147,000	177,000	169,600	169,600	771,200
Support	132,000	107,000	96,000	86,000	87,000	508,000
TOTAL	990,000	1,104,000	1,123,000	1,080,600	1,066,600	5,429,200
Contributions						
DOE	924,000	1,050,500	1,075,000	1,037,600	1,063,100	5,150,200
NCI	66,000	53,500	48,000	43,000	43,500	254,000
NCI Personnel**						

*Assumes an average of $200 per man-month

**Total contribution to all projects listed on summary page

Manpower Requirements

Task	1996	1997	1998	1999	2000	TOTAL
Ukraine Thyroid						
Manage and administer project	63	63	63	63	63	315
Establish cohort	72	72	72	50	50	316
Arrange appearance of cohort	60	60	60	60	60	300
Perform clinical evaluations	180	360	500	500	500	2,040
Perform diagnostic confirmation	15	30	40	40	40	165
Plan data flow + write software	40	40	40	45	45	210
Reconstruct thyroid doses	60	60	60	40	40	260
TOTAL	490	685	835	798	798	3,606
X $200	98,000	137,000	167,000	159,600	159,600	721,200
Plus 10K Administration	108,000	147,000	177,000	169,600	169,600	771,200

UKRAINE LEUKEMIA STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	300,000	120,000	Projection			420,000
Local assistance	43,600*					43,600
Support	175,000	122,000	After Completion of			297,000
TOTAL	518,600	242,000	Feasibility study			760,600
Contributions						
DOE	431,100	181,000				612,100
NCI	87,500	61,000				148,500
NCI Personnel**						

*Covers 18 months period at $200 per man-month

**Total contribution to all projects listed on summary page

UKRAINE-LEUKEMIA PROJECT

Manpower Requirements

Activity	Man-years/18 months feasibilit study period	
	1996-97	1998-2000
1. Sampling	1.0	
2. Dosimetry	2.5	
3. Leukemia/Lymphoma Study	2.5	To be determined at a later date.
4. Pathogenesis/Mol. Biology	1.0	
5. Tracing Effort	2.0	
6. Organization/Planning Tasks	1.0	
7. Management	4.0	
Total	14.0	

Remuneration at 200/month	$33,600
Administrative Overhead	10,000
TOTAL	$43,600

Working sheet

S U M M A R Y

	1996	1997	1998	1999	2000	TOTAL	
Belarus Thyroid Study	556,000	535,200	759,200	945,600	1,145,600	3,941,600	ok
Ukraine Thyroid Study	990,000	1,104,000	1,123,000	1,080,600	1,106,200	5,403,800	ok
Ukraine Leukemia Study	656,518 ~~518,600~~	415,200 ~~242,000~~	365,200	353,200	298,657	2,088,755 ~~1,260,000~~	
TOTAL	~~2,064,600~~ 2202518	~~1,881,200~~ 2,054,400	~~1,882,200~~ 2,247.4	~~2,026,200~~ 2,379,400	2,550,457 ~~2,251,800~~	~~10,106,000~~ 11,434,155	
Contributions							
DOE	1,837,600	1,717,700	1,785,700	1,939,700	2,164,800	9,445,500	
NCI	227,000	163,500	96,500	86,500	87,000	660,500	
NCI Personnel*	495,000	508,225	520,930	533,952	547,299	2,606,222	

*Total contribution to all projects
Assumes an average of $200 per man-month

UKRAINE LEUKEMIA STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	419,118	120,000	100,000	100,000	40,637	779,755
Local assistance	65,400	173,200	173,200	173,200	173,000	758,000
Support	172,000	122,000	92,000	80,000	85,000	551,000
TOTAL	656,518*	415,200	365,200	353,200	298,637	2,088,755
Contribution						
DOE	570,518	354,200	319,200	313,200	256,137	1,813,255
NCI	86,000	61,000	46,000	40,000	42,500	275,500
NCI Personnel**						

* Covers 18 months period at $200 per man-month

** Total contribution to all projects listed on summary page

BELARUS THYROID CANCER STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	300,000	300,000	500,000	700,000	900,000	2,700,000
Local Assistance						
Minsk	79,000	102,200	122,200	118,600	118,600	540,600
Moscow	30,000	35,000	40,000	40,000	40,000	185,000
Support	147,000	98,000	97,000	87,000	87,000	516,000
TOTAL	556,000	535,200	759,200	945,600	1,145,600	1,941,000

Total NCI Personnel contribution listed on the summary page.

UKRAINE THYROID CANCER STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	750,000	850,000	850,000	850,000	850,000	4,150,000
Local assistance*	108,000	147,000	177,000	169,600	169,600	771,200
Support	132,000	107,000	96,000	86,000	87,000	508,000
TOTAL	990,000	1,104,000	1,123,000	1,080,600	1,066,600	5,429,200
Contributions						
DOE	924,000	1,050,500	1,075,000	1,037,600	1,063,100	5,150,200
NCI	66,000	53,500	48,000	43,000	43,500	254,000
NCI Personnel**						

*Assumes an average of $200 per man-month

**Total contribution to all projects listed on summary page

Budgetary projections for Equipment and Supplies

		1999		2000	
		Available	Need	Available	Need
BelAm Thyroid					
Screening:	Mobile team				
	Ultrasound equipment		50,000		***
	Centrifuge		15,000		***
	Laptop PC	3,000			
	Phlebotomy supplies	5,000			5,000
	Stationary unit				
	Filing cabinets	5,000			
	Microscope		15,000		***
	Phlebotomy supplies	5,000			5,000
DCC/Epidemiology					
	Voice mail machines	1,000			
	Upgrade computer net	10,000			10,000
	Resupply: paper lables cartridges	5,000			10,000
	Maintenance contract		25,000		25,000
Dosimetry	Complete unfilled orders		60,000		***
Clinical laboratory					
	Resupply phlebotomy	10,000			10,000
	Resupply hormone assays	25,000			25,000
Gomel Extension					
	Ultrasound equipment		50,000		***
	Centrifuge		10,000		***
	Computers		10,000		***
	Supplies: lab, clinical. Off.		10,000		10,000
	Microscope		10,000		***
		69	255		100

*** = If not provided in FY1999, will need it in FY 2000

UkrAm Thyroid	1999		2000	
	Available	Need	Available	Need
Screening: Mobile laboratory	100,000	50,000		
Microscope	15,000			
Computers	5,000			5,000
Phlebotomy Resupply	5,000			5,000
Filing cabinets	5,000			
Clinical laboratory				
Phlebotomy resupply	5,000			10,000
Hormone assay resupply	25,000			35,000
DCC/Epidemiology				
Voice mail machines	1,000			
Resupply: paper				
lables				
cartridges	10,000			15,000
Maintenance contract	25,000			25,000
Outlying feeder organizations				
PC's				60.000
Office supplies				30.000
Replacement, upgrading equipment				25,000
	196	50		210

UkrAm Leukemia

No additional funds anticipated to be needed in FY 1999, until completion of Phase I.

If Phase II will be implemented, funds for FY 2000 will be required to:

Set up local feeder stations	100-150,000
clinical assay reagents	20,000
Freezers	30.000
Additional computers	25,000
Office supplies	15,000
Dosimetry supplies	50.000
	240 - 290

ATTACHMENT

28

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20205

Dr. Walter Stevens
Associate Dean for Research
1C404 Medical Center
College of Medicine
University of Utah
Salt Lake City, Utah 84132

Dear Dr. Stevens:

This letter and the enclosures originally were intended to reach you within 2 months following our site visit at the University last April, but, for a variety of reasons, their transmittal had to be delayed until this time. Even though we have discussed the content of this material by telephone, and, as a consequence, the University has initiated certain actions, this letter and the enclosures reflect the reviewers' assessment of the circumstances and information presented, reviewed and discussed at that time.

Accordingly, enclosed (Enclosure A) is a summary of the reviewers' comments resulting from the site visit at the University of Utah on April 24-25, 1985, for the purpose of a peer review of the National Cancer Institute (NCI) Contract N01-CO-23917, "Assessment of Leukemia and Thyroid Disease in Relation to Fallout in Utah."

As a result of the comments, and in keeping with the opinions expressed by the University and the University's Advisory Committee, the NCI adopts the following priorities, and is proposing that the Statement of Work be revised (Enclosure B) accordingly:

1. Thyroid Cohort Study--highest priority. Extensive management and technical issues must be addressed and resolved.

2. Leukemia Case-Control Study--very high priority. Issues related to dosimetry and adequacy of control subjects must be addressed and resolved.

3. Thyroid Case-Control Study--low priority. Defer indefinitely until such time as the thyroid cohort study is satisfactorily completed and the leukemia case-control study is well on its way to completion. The study should be conducted only if remaining time and resources are adequate to complete the effort.

4. Leukemia Cohort Study--terminate immediately.

The University should review the proposed revised Statement of Work, and in light of the above, revise its renegotiation request of March 19, 1985, with a separate written justification for comments not considered appropriate.

The NCI will consider the resubmission (including objectives, protocols, methodologies, proposed analyses, equipment, budget, and administrative, managerial and technical personnel, and defined reporting dates for intermediate milestones) in the context of the proposed revision of the Statement of Work. The NCI anticipates that the Contractor will review the revised proposal of September 23, 1981, and identify (1) any deviation from the relevant pages cited in the proposed revised Statement of Work, Article I, Paragraph A, and (2) the manner in which activities previously included under "Subcontractor Work Plans" (see Article I, Paragraph A) are to be accomplished. Estimated costs to complete the proposed revised Statement of Work should be provided using the enclosed format (Enclosure C). Again, any renegotiation must take place within the budgetary and time constraints of the existing contract.

In keeping with both the reviewers' opinions and discussions with the University Administration, your revised proposal must address the need, and identify plans, to revise and improve project management and management practices, including the acquisition of a senior scientist with a proven record of managerial and relevant technical accomplishment. In view of past and present difficulties, as indicated in the reviewers' comments, this would be expected to contribute substantially to the resolution of many of the problems facing this contract.

Both the University and the NCI continue to find the lack of progress and numerous unresolved managerial and technical issues associated with this contract less than satisfactory. When a peer review of the project at this point in the contract period results in the type of comments appended, questions must be raised as to the managerial and technical capabilities and/or commitment of the investigator(s) with respect to this contract. Many of these issues have been raised in correspondence with the Principal Investigator over the past two years. However, the NCI anticipates that with improved management and technical expertise, and with the increased attention being given to the contract by the University, the two highest priority studies within the contract can be satisfactorily completed. It has been more than three years since this contract was awarded, and it is time to realistically identify the resources, and expertise, by means of which the University intends to achieve the successful and timely completion of this contract.

We look forward to receiving the University's response to accomplish the proposed revised Statement of Work, and to continue working with you on this important study.

Sincerely,

Nancy Coleman

Nancy Coleman
Contracting Officer
Cancer Etiology Contracts Section
Research Contracts Branch, OD
National Cancer Institute

Bruce W. Wachholz

Bruce W. Wachholz, Ph.D.
Chief, Low Level Radiation Effects Branch
Division of Cancer Etiology
National Cancer Institute

Enclosure A

SUMMARY OF REVIEWERS' COMMENTS

on

National Cancer Institute Contract NO1-CO-23917

"Assessment of Leukemia and Thyroid Disease in Relation to Fallout in Utah"

The National Cancer Institute (NCI) carried out a site visit at the University of Utah on April 25 and 26, 1985, in order to permit peer reviewers to hear directly from and discuss with the investigators and the University Administration progress, problems, and priorities pertaining to NCI Contract NO1-CO-23917. This visit was a part of the review of the University's recommendations and priorities which were submitted by letter of March 19, 1985, to serve as a basis for renegotiation of the Contract.

The following observations and conclusions of the reviewers evolved from that site visit:

1. Review Presentation. Since the peer site reviewers had little or no knowledge of the project or of many of its staff prior to the site visit (other than copies of annual reports, the University's submitted material, the University Advisory Committee Report, and previous correspondence), they were dependent upon and influenced by the quality and substance of the presentations made by the investigators and staff. With few exceptions, the presentations were disappointing; the presentors were unprepared, unrehearsed, incomplete, and occasionally at variance with one another. Given the time, effort and monies already expended on this project, a well-prepared program with clear visual aids, unequivocal and justified approaches to the choice of analytical tools, well-reasoned methodology for using dose or exposure data, and well-defined objectives, protocols and accomplishments were expected.

2. Management. Although the project is receiving more attention from management than heretofore, particularly through the efforts of Dr. Walter Stevens, it is obvious that other duties preclude his full-time attention to this contract. Although his involvement has led to significant improvement, it is clear that there remains a lack of strong and effective day-to-day technical and administrative direction, little or no unity of effort, and no well-defined protocol with milestones leading to a successful and timely completion. This is particularly distressing considering the size, scope, complexity, sensitivity and multi-disciplinary nature of this project. If a modified scope of work, even at a reduced level, is to be completed successfully and with technical excellence, the leadership of the project must be improved; no single factor is considered to be more important to its success. This lack of effective management was evident in the absence of agreement and cooperation among present investigators, the absence of clear and defined responsibilities, the inability to resolve differences of opinion, and a lack of planning and decision-making capability.

Each of the project tasks requires a management plan, in writing, which is considerably more comprehensive than a simple time-line. Specific and realistic goals for each component and activity of the project must be clearly identified as to purpose, protocols, methodologies, use, influencing factors, uncertainties, etc., including what is due, to whom it is due, when it is due, in what format it is due, and the person responsible for it, together with a master plan of how it all interrelates, including specific data analyses and presentation formats.

For each component there also should be a quality assurance plan, including a written guide, documentation of all data bases, algorithms, linkage methods, etc., means to preserve data and program codes, and documentation of data verification and quality control procedures.

It is important to plan analyses well in advance of the time that data will be available; any conclusions reached from this study will be more convincing if the procedure for analysis is defined before the data are examined. Such a written protocol for analysis should be reviewed by qualified statisticians and epidemiologists prior to the completion of data collection.

Managerial and technical leadership on a day-by-day basis is needed to guide, unify, and coordinate the various investigators, and to motivate the staff to function as a team rather than to act as separate and competing entities. The lack of administrative and technical direction was particularly noticeable with respect to the dosimetric components of the study, especially those related to the exposure of persons to radioactive iodine, and the corresponding estimate of the thyroid dose. Accordingly, the reviewers recommend that the University obtain the services of a senior scientist who has a proven managerial and technical record of accomplishment, has a background in all relevant technical aspects of the project, especially those pertaining to the dosimetry (e.g., a highly competent physicist or biophysicist also skilled in environmental dose assessments), and who will be committed full time to the management and technical direction of this contract, and given appropriate authority.

The reviewers are of the opinion that the dosimetry is a vital and integral component of this study, without which any results will be greatly diminished in value (i.e., if any thyroid abnormalities are observed the results will lead only to speculation if there is no quantitative relationship to fallout). If thyroid dosimetry sufficient to meet the objectives of the contract cannot be carried out, the objectives of the contract are compromised, and continuation of the contract should be reevaluated.

3. Thyroid Cohort. It is generally agreed that this study is potentially the strongest study in the project and should receive the highest priority of resources and effort. Therefore it was surprising and distressing to note that after 3 years the planning and implementation of the thyroid dosimetry still appears to be rather preliminary.

A number of observations and recommendations follow:

a. Responsibility for all aspects of the thyroid dosimetry must be firmly fixed and clearly defined.

b. There is concern that estimates of exposure to radioiodine are proceeding from basic principles, when in fact much work has already been carried out and evaluated by the scientific community. Advantage should be taken of currently existing data and dose methodologies that are available without attempting to derive all of the methods from basic concepts. Consequently, there is no need to reinvent radioiodine dosimetry in order to be "independent"; however, the existing methodologies must be assessed, and the selected methodology must be credible, defensible, and documented. To date there is little evidence of such an effort, and the results accordingly do not appear to be commensurate with the time, effort, and dollars expended.

c. If the thyroid dosimetry is to be completed within the constraints of the contract, the reviewers consider it necessary that use be made of the data, methodologies, and findings of other relevant studies (e.g., the Department of Energy [DOE] Offsite Radiation Exposure Review Project). These other studies should be reviewed for accuracy and scientific integrity, and applied as appropriate to this project. Despite the fact that one University staff member is on the DOE Dose Assessment Advisory Committee (DAAG), another attends all of the DAAG and DOE Working Group meetings, and the DOE Scientific Director and the scientist responsible for DOE environmental transport models both are members of the University of Utah Advisory Committee for this project, there is no apparent close working relationship between the two projects or verification/evaluation of each other's efforts.

d. Relevant to (c) above, the reviewers recommended that the University of Utah make arrangements with the Department of Energy to assess and, if appropriate, to use the more accurate Town Data Base (TDB) rather than the Survey Meter Data Base.

e. The reviewers noted that no sensitivity analyses have been carried out to establish which variables are the most important and/or on which the levels of uncertainty can be meaningfully reduced. Without such analyses, efforts remain diffuse and unfocussed. Preliminary sensitivity analyses would help to determine which variables are important and to establish both a good data base and an appropriate algorithm for incorporating these variables.

f. Particular emphasis must be given to defining the uncertainty of the specific steps of any dose assessment. At some point the uncertainties must be addressed at least in qualitative terms, with quantitative estimates of uncertainty being provided to the extent possible.

g. The reviewers question whether ultimately it will be possible to assign an individual dose that will be much more reliable, given all of the uncertainties, than a dose assigned on the basis of the ORERP internal dose file for the thyroid dose which is based upon life style, location, age and sex factors. Independent evaluation and verification of this approach may be a productive approach to the dosimetry issue. While milk consumption by an individual would be expected to be important in determining an individual dose, the extent to which there will be any concommitant improvement in the reliability of the dose estimate is not known. Here, again, a sensitivity analysis would have been helpful in determining whether or not large expenditures of resources should be committed for this purpose.

h. It appears that little or no coding of dosimetry data for machine processing has been done. This is attributed, at least in part, to the lack of any organized and detailed description of how the data are to be treated in arriving at thyroid dose estimates.

i. There is serious concern that the thyroid cohort control group is not being given the same consideration as the exposed group. At least some sort of group or location estimate of dose should be provided for the Arizona subjects, rather than to assume that their exposure was zero. It would be desirable for calculations of dose to these subjects to be done in the same manner as that used for the exposed group.

j. The presentation and definition of the thyroid dosimetry algorithm were not clear. Subtasks that the reviewers did not find included:

- Expression of the algorithm in terms of quantities, including appropriate mathematical notation.
- Definition of all links with the survey questionnaires; identification of how the data from each question will be handled.
- Documentation of the methodology and of any computer program to be used.
- Validation of the milk contamination model; comparisons of predicted milk concentrations to those from documented fallout occurrences in southwestern Utah.
- Evaluations of the overall uncertainties in the thyroid dose prediction.
- A detailed flowchart.

k. Particular attention should be given to those cohort subjects who moved into the area after the period of fallout because both they and the "exposed" group reside in the same general geographical area, and may, consequently, be tested "blind" by the examiners. In addition, the thyroid dosimetry may be more attainable on this group of controls, relative to the "exposed" group, than on the Arizona control group.

l. Consideration should be given to interviewing both subjects and their parents on the "Milk Intake" interviews to provide a validity check.

m. The reviewers expressed concern regarding the validity of the "Milk Survey" and the use to which the results of the Survey will be put. Specifically, while numbers will be obtained from the Survey, the possibility exists that these numbers may be inaccurate to varying degrees and therefore may compromise the usefulness of the study. One reviewer suggested that an alternative to this approach is to divide milk production into three categories based on the source of milk as determined by the cohort in the survey: (a) the backyard cow; (b) small processor (a few farms); and (c) large processor (many farms that may include some imported milk). One might then use existing data and records of processors and former processors to determine the amount of dilution. In addition, the weather data could be checked to make inferences about crop productivity. On the basis of this information persons would be assigned a dose that would include milk consumption data and the estimated concentration of radioiodine in milk. Cohorts who derive milk from more than one source during the study period would have a weighted average concentration. This approach was thought to be at least as, and perhaps more, defensible than the method currently being proposed.

n. A number of detailed comments include:

- An acceptable method of estimating intake for a group of animals may be inappropriate and inaccurate for the individual animal. This must be considered if an evaluation is made of one or a few cows as compared to a herd.

- If nutrient balancing is to be used to reconstruct intake, dry matter and total digestible nutrients must also be factored in.

- Extensive surveys and calculations aimed at those pathways which do not contribute significantly to the dose should be eliminated. It should not take long to do a few calculations to determine whether the attention to goats and vegetables is justified.

- Have the studies carried out in the United Kingdom regarding iodine dose estimates (e.g., the Windscale accident, recent assessments by the National Radiological Protection Board) been reviewed? They may provide insight and save resources.

- Was sprinkler irrigation employed at the time, and to what extent did this (and rainfall) reduce estimated dose in associated areas?

o. The information presented on the findings of the clinical examinations was unexpected. These limited and very preliminary data show that there is not much difference between the "exposed" group and the "unexposed" group, but that both differ significantly from generally accepted prevalence of abnormalities in the general population. At some point this will need to be addressed if the preliminary observations hold up.

4. Leukemia Case-Control. The reviewers are in agreement with the redirection of the methods to estimate doses, i.e., to use the Environmental Measurements Laboratory soil and gummed film data sets rather than attempt to develop extended fallout patterns throughout Utah based on modelling and existing contour data. There are, however, several factors which are extremely important in estimating these doses and dose rates, which appear to have received little attention, much less resolution, by the project staff:

- The large uncertainties already associated with the estimates of exposure.

- The significance of variations in levels of background radiation.

- The errors due to the necessary interpolation and extrapolation from one location to another.

- Whether the Nevada Test Site fallout contribution to the dose is the dominant or even a major dose component.
- The variations in the shielding factor associated with differences in lifestyles and in the characteristics in dwellings.
- The appropriate factors for converting air dose to bone marrow dose.
- The relevance of medical exposure history.

The reviewers are of the opinion that all of the above must be assessed and evaluated if there is to be any determination of whether an assigned dose is significantly greater than zero for the fallout related doses. Given that these variables and their associated uncertainties must be accounted for in any interpretation of results, that these sources of variation are probably of equal or greater magnitude than the variation associated with the fallout, and that they undoubtedly will have an impact upon the plausibility of any purported association with fallout, it is disturbing to the reviewers that the investigators apparently have neither identified nor addressed these problems.

A major concern about this study is the possibility that intrinsic biases may be associated with the planned control group consisting of decedents. For example, it was indicated that several of the major causes of death, which will figure prominently in the control group, many have rural-urban biases. The rationale for the assertion that the LDS death registry (as opposed to the state death registry) would avoid such biases was not apparent to the reviewers. Since one would expect to see only small, if any, differences in exposure between the cases and controls, any subtle biases such as this one could well mask or falsely simulate such differences if fallout exposure levels may by coincidence be correlated with urban-rural patterns in Utah. Even if exposure does not follow clear urban-rural lines, there would nevertheless appear to be some potential for bias.

The reviewers believe that it should be possible to calculate a population weighted dose separately for urban and rural areas (assuming the same residence throughout the period). Then, using what is known about differences in death rates between urban and rural areas, one could estimate the potential for bias for each of several causes of death (e.g., the dose distributions and residential patterns could be compared for controls dying of cancer, heart disease, accidents, and other causes). Analyses using only certain subgroups of controls (based on cause of death) could be conducted; if results are essentially the same regardless of which controls are used, one obviously is in a much stronger position than if results depend on this choice. The use of cancer deaths as controls is a special concern, and the comparison of exposures associated with these deaths with those associated with other causes is of special interest. Hence, it is important that plans be formalized for (a) an additional control group comprised in such a way as to minimize known potential biases, and/or (b) additional analyses of the projected control group so as to evaluate the magnitude and direction of possible biases. Since the addition of extra controls is relatively inexpensive in this study (i.e., it does not involve costly elements such as personal interviews), it would seem worthwhile to consider a second control group, perhaps more than four controls per case, to allow separate comparisons for various causes of death (e.g., based on a subset of causes of death which are relatively independent of lifestyle/socioeconomic/urban-rural factors). It may not be possible to maintain the matched design in doing so, but this is not thought to be a serious problem since stratifying on the matching variables will accomplish the same thing.

Since individual dose estimates will be available, the data should be analyzed in a way that treats dose in a quantitative fashion. There is no need to group or categorize exposures although probably not too much would be lost as long as several exposure categories are used and trends examined. A preference, at least for the initial analyses, would be Mantel's trend test. In addition, it may be useful to present observed and expected numbers of cases in various categories. This might lead to a decision to exclude certain causes of death in conducting statistical tests. At a minimum, this source of bias should be considered in the discussion and interpretation of results.

In the contract renegotiation proposal it is proposed to perform subanalyses according to age at fallout and induction period. It is important to plan analyses well in advance of the time that the data will be available. It may take some time to decide on appropriate techniques, and to adapt software to carry out the needed computations; however, these activities should be completed prior to the availability of the data. This planning process should include procedures to translate the "raw" data into a data file suitable for analysis.

To avoid the temptation of ad hoc analyses for such factors as dose, age at the time of fallout, or time after fallout (e.g., by first examining the data to determine the most significant split), the investigators should specify in advance, in writing, exactly what comparisons will be made in the subanalyses before examining the data, as indicated previously [see Item (2) above]. Developing this plan does not necessarily exclude analyses not in the original plan, but results of analyses that have been specified a priori will naturally carry a much higher level of credibility.

5. Thyroid Case-Control. The reviewers agree with the University that this study should receive a very low priority. The recommendation is that it should be deferred until (a) the thyroid cohort study is complete, and (b) the leukemia case-control study is near completion. At that time the study may be reconsidered if sufficient resources remain to complete the study (i.e., time and funds).

6. Leukemia Cohort Study. In keeping with the low priority given this study by the University and the University's Advisory Committee, the reviewers recommend that this study be terminated for the following reasons: 1) it would add little information to that obtainable in other parts of the project, 2) the massive data base required is more appropriate for objectives not germane to this contract, 3) it is consuming resources far out of proportion to its scientific contribution to understanding the health effects of fallout in Utah, and 4) the associated funds could, in part, be more effectively used to supplement other studies in the project.

ATTACHMENT

29

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

TELEFAX MESSAGE

TO:
Telefax: 510-424-6208
Name & Address:
Sheilah

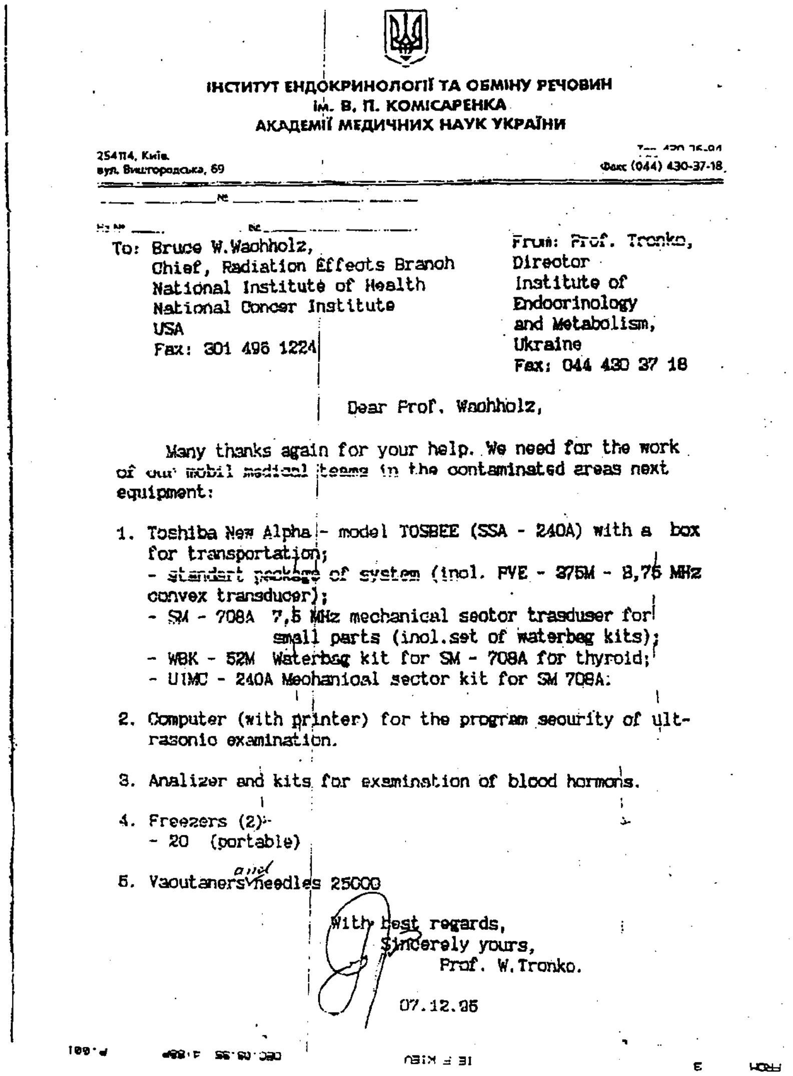
FROM:
Telefax: 301-496-1224
Name:
Bruce

Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Room 530

DATE: 1/19

NUMBER OF PAGES INCLUDING COVER: 6

NOTE: 1st 3 pages — Ukraine Thyroid Study
last 2 pages — Ukraine Leukemia Study
Please look it over but we have not yet "okd" anything, although it is likely.



ІНСТИТУТ ЕНДОКРИНОЛОГІЇ ТА ОБМІНУ РЕЧОВИН
ім. В. П. КОМІСАРЕНКА
АКАДЕМІЇ МЕДИЧНИХ НАУК УКРАЇНИ

254114, Київ,
вул. Вишгородська, 69

Тел. 430 36-04
Факс (044) 430-37-18

№

На № ____ від

To: Bruce W.Wachholz,
Chief, Radiation Effects Branch
National Institute of Health
National Concer Institute
USA
Fax: 301 496 1224

From: Prof. Tronko,
Director
Institute of
Endocrinology
and Metabolism,
Ukraine
Fax: 044 430 37 18

Dear Prof. Wachholz,

Many thanks again for your help. We need for the work of our mobil medical teams in the contaminated areas next equipment:

1. Toshiba New Alpha - model TOSBEE (SSA - 240A) with a box for transportation;
   - standart package of system (incl. PVE - 375M - 3,75 MHz convex transducer);
   - SM - 708A 7,5 MHz mechanical sector trasduser for small parts (incl.set of waterbag kits);
   - WBK - 52M Waterbag kit for SM - 708A for thyroid;
   - UIMC - 240A Mechanical sector kit for SM 708A.

2. Computer (with printer) for the program security of ultrasonic examination.

3. Analizer and kits for examination of blood hormons.

4. Freezers (2)-
   - 20 (portable)

5. Vacutaners and needles 25000

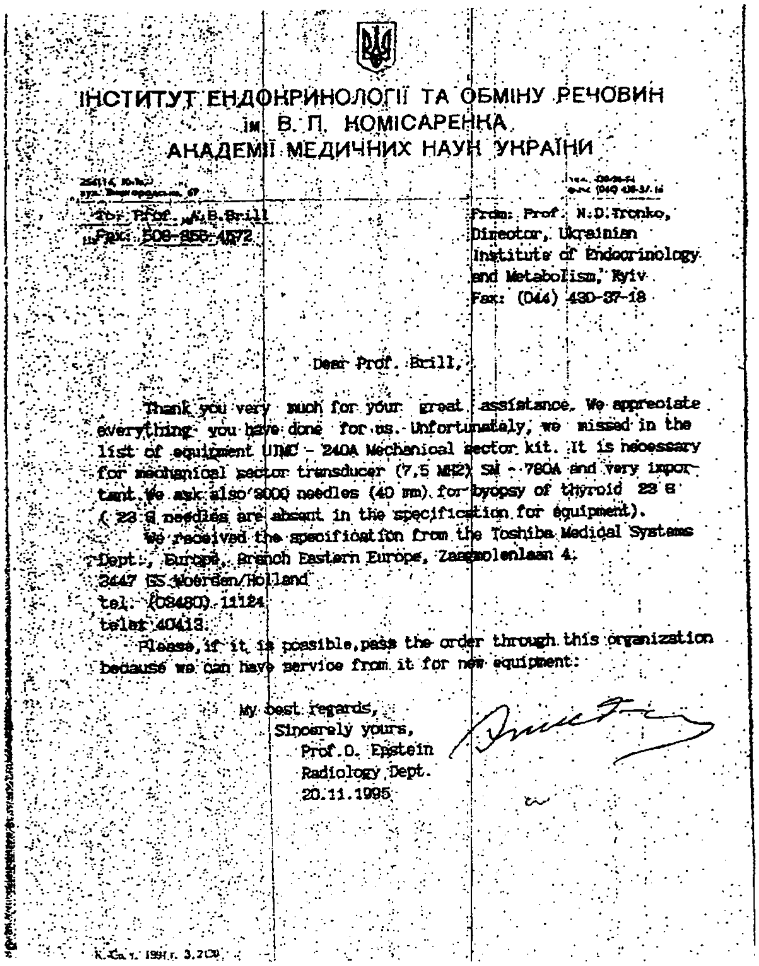
With best regards,
Sincerely yours,
Prof. W.Tronko.

07.12.95

FROM 3 IE F KIEV DEC.08.95 4:58P P.001

- PVF-738H 1 spec.	'Micro' convex transducer for interoperative use, (horizontal type) Dual frequency 7,0/5,0 MHz radius 80 mm, viewing angle 27 degr. (PWD/CFM)
- UAGV-020A 2 spec.	Biopsy guide for PVF-738H/738F
- TP-8700 1 spec.	B/W videoprinter incl. 2 cartons a 5 rolls printer paper (B-510)
- SG-MD830 1 spec.	Super VHS videorecorder, semi-professional incl. 1 carton a 10 Super VHS videotapes
Delete PSP-37FT 1 spec.	Recommended transducer for routine examination, 3,75 MHz., 64 elements (PW/steering CW Doppler/CFM)
Delete UIPS-141A 1 spec.	Third probe selecter channel "C" (to be used with "PSF" probe series) (for cardiological exam.)
- B-510 3 spec.	printer paper for TP-8700 (1 carton a 5 rolls)
- SG-1050 10 spec.	Sonogel, container a 5 litres
- Biopsy/21	Biopsy needle 21G x 2000
- Biopsy/22	Biopsy needle 22G x 1000

2. TOSHIBA NEW ALPHA - model TOSBE (SSA-240A)
- standard package of system (incl. PVE-375M (3,75 MHz convex transducer))



ІНСТИТУТ ЕНДОКРИНОЛОГІЇ ТА ОБМІНУ РЕЧОВИН
ім. В. П. КОМІСАРЕНКА
АКАДЕМІЇ МЕДИЧНИХ НАУК УКРАЇНИ

To: Prof. A.B.Brill
Fax: 508-856-4572

From: Prof. N.D.Tronko,
Director, Ukrainian
Institute of Endocrinology
and Metabolism, Kyiv
Fax: (044) 430-37-18

Dear Prof. Brill,

Thank you very much for your great assistance. We appreciate everything you have done for us. Unfortunately, we missed in the list of equipment UMC - 240A Mechanical sector kit. It is necessary for mechanical sector transducer (7,5 MHz) SM - 780A and very important. We ask also 2000 needles (40 mm) for byopsy of thyroid 23 G (23 G needles are absent in the specification for equipment).

We received the specification from the Toshiba Medical Systems Dept., Europe, Branch Eastern Europe, Zaagmolenlaan 4.
3447 GS Woerden/Holland
tel. (03480) 11124
telex 40413.

Please, if it is possible, pass the order through this organization because we can have service from it for new equipment.

My best regards,
Sincerely yours,
Prof.O. Epstein
Radiology Dept.
20.11.1995

List of equipment and reagents which should be
supplied rank first on the American-Ukrainian
Programme "Leukemiae-Lymphomas"

HEMATOLOGY

1. Diagnostic kits for diagnostics of acute leukemiae and lymphomas.
2. Microscopes.
3. Refrigerating centrifuges.
4. Regrigerators.
5. Slide subjectal and covering.
6. Needles for implementation of sternal punctions and trepanobiopsy.
7. Computer.
8. Containers for transportation.

EPIDEMIOLOGY AND DOSIMETRY

1. Computers.

SUBSTANTIATION

for obtaining of equipment necessary for implementation of hystological investigations on the American-Ukrainian Programme "Leukemiae and Lymphomas"

For successful implementation of pilot phase of the American-Ukrainian Programme "Leukemiae and Lymphomas" the Ukrainian Side asks the American Side to allocate additional funds for obtaining of equipment for implementation of hystological investigations of lymphomas.

List is enclosed.

1. Microscope fluorescent "Axioscope", firm "Carl Zeiss", cost 30 000 $.
2. Station for filling of parapphine blocks HMP-110, firm "Micron", 23 000 $.
3. Automate for dying HMS 70, firm "Micron", 22 000 $.
4. Microtome HM-360, firm "Micron", 20 000 $.

Department of Energy
Germantown, MD 20874-1290

FEB. 15 1996

Dr. Bruce Wachholz
Chief, Radiation Effects Branch
National Cancer Institute
6130 Executive Boulevard, Rm. 530
Rockville, Maryland 20852-7391

Dear Dr. Wachholz:

Cherie Gianino and I found our trip to Minsk, Belarus, January 20-25, 1996, in which we met with the scientists and the Government officials involved in the Belarus/American (Bel/Am) Thyroid Study and visited the facilities, very informative. Our visit enabled us to gain a better understanding of the status and the needs of the project.

Following a review of our visit and detailed discussions on the long-term (30-year) Bel/Am Thyroid Study with Dr. Paul Seligman, Mr. Frank Hawkins, and the staff of the Office of International Health Programs (EH-63), we have determined that we have a number of general concerns and specific requests relating to the project. These are outlined below.

General Concerns:

- o Provision of U.S. funds to Belarus for personnel support for the Byelorussians working on the Bel/Am study will result in a fundamental change in the agreement signed with the Belarus Government. This agreement and the Bel/Am Thyroid Protocol state that Belarus will support all Byelorussians working on this project. A commitment to provide Belarus personnel support also significantly increases the cost to the United States, and to the Department of Energy (DOE) in particular, at a time when DOE's budget is being cut severely. You have indicated the National Cancer Institute (NCI) is unable to provide any additional funds. Furthermore, the possibility that a portion of the $500,000 of matching NCI/DOE funds managed by the NCI can be used for Belarus personnel support has not been adequately discussed.

- o The most recent budget estimates that you presented to our office for funds required for personnel support in Belarus are more than double what you presented to us several months ago. This has severely compromised our fiscal year 1996 budget projections for this project.

- o The personnel needs in Belarus will escalate considerably over the next 3 years as the number of children who are actively being followed increases. No other U.S. agency has agreed to absorb any of these costs. Such a commitment has the potential of compromising all the programs supported by our office.

- As you inferred in your January 31, 1996, letter, any financial commitments we make in Belarus will need to be repeated (in some cases on a larger scale) in the four studies that are either ongoing or being planned in Ukraine.

- We continue to be concerned about the numerous reports of delays and difficulties in moving the project forward.

- Finally, the oversight committee for this protocol, signed in May 1994, is not established. The scientific review of this protocol carried out by the NCI in 1993(?) emphasized that, "the oversight group should be established as soon as possible so that the study may benefit from the advice and guidance of an interdisciplinary and bilateral scientific body of experts." This lack of oversight is of particular concern to us because this project is such a long-term (30-year) commitment, and it does not have clearly defined stages at which milestones need to achieved and the project reassessed.

Each of these concerns has reinforced our view that we need to proceed cautiously with regard to providing direct personnel support to Belarus. That is what I did during my visit to Belarus. I regret if this has caused you any inconvenience, but it would be imprudent for our office to make long-term financial commitments that we cannot meet. As always, *our goal is to support this important project, while assuring the efficient and prudent stewardship of all U.S. funds and resources.*

Specific Requests:

In order to fulfill our budgetary and managerial responsibilities EH-63 would like the following information.

- **Progress Report.** We would like to receive a progress report for the Bel/Am Thyroid Study that includes all progress made since the signing of the protocol. In this context, we also would like to work with you and set up a future schedule for completing progress reports that would be distributed to all the agencies supporting this project.

- **Organizational Chart.** During our meetings in Belarus, Dr. Krisenko, the Belarus Project Leader, requested that we provide him with an organizational chart of the American scientists who will be working on the study. Please send us a copy of the chart including the responsibilities of each of the individuals.

- **Oversight Committee.** Dr. Krisenko noted during our group meetings in Belarus that he is anxious to convene the Advisory Committee for this project. I understand his desire, since as outlined in the protocol, the Advisory Committee was supposed to review the progress of the project at the end of the project's first year, which was in May 1995. Dr. Krisenko provided us with the list of members for the Belarus half of the Advisory Committee and requested that we submit our list of American Advisory Committee members to him as soon as possible. We would like to work with you and the NCI staff to identify who in the NCI will be in charge of putting together the initial American Advisory Committee, and to determine when that individual will consult with us on the composition of the committee

- **Milestones/Funding Agreement for Belarus Support.** As we discussed in Geneva in November 1995, and on several occasions before and after the Geneva trip, in order for us to determine an appropriate level of funding for scientific support for Byelorussians for the first year of the project, we need a completed set of milestones that are written with clear deliverables for each of the tasks. I was quite pleased that after our discussion on January 22, 1996, the evening we arrived in Belarus, that you, Dr. Lynn Anspaugh and Dr. Andre Bouville were able to generate draft milestones for the first 3 months, which could be presented to Dr. Krisenko the next day. Similarly, please provide us with adequate milestones that are clearly tied to individual work and people-months for the next year.

- **Budget Information.** In our effort to ensure that our limited funds are put to the most efficient use, we want to determine if there is an overlap of efforts supported by DOE (through direct DOE funding to the national laboratories and other contractors) with those efforts being supported by the NCI (using the matching $250,000 that NCI and DOE contributes each year). Your budget submission for 1996 (as well as for 1995) only specifies general categories of expenses and does not provide us enough information to resolve this issue and to understand how you are spending the $500,000 of matching funds. We need a more detailed budget from you for 1996. In this context, we have incurred significant management costs for the Bel/Am Thyroid Study and would like to receive a copy of Everet Mincey's contract and a description of his general duties to ensure that there is no duplication of management efforts.

- **Management.** We completely agree with the view you expressed in your letter dated January 31, 1996, that we need to clearly define the responsibilities of the DOE and the NCI in managing this project. To achieve that goal, we would like to work with you and the Nuclear Regulatory Commission (NRC) to generate a list of the management responsibilities of the NCI and the management responsibilities of the DOE. It is particularly important to our office that DOE's responsibilities are clearly defined and accepted by the all the involved parties, because, as your know, **DOE is the agency legally accountable for this project.** To help us begin this process, please send us a draft list of NCI's responsibilities as you envision them. We also would appreciate receiving clarification on the role of Dr. David Becker, the Chairman of the U.S. Committee, and the rest of the scientific working group.

As you know, we have many similar concerns regarding the thyroid and leukemia studies in Ukraine. In fact, we have temporarily postponed our planned trip to Ukraine (scheduled for February 22, 1996) until some of these issues are resolved. Because we share your concern about moving both these projects along in a timely manner, we would appreciate receiving the requested information by March 1, 1996.

Finally, I appreciated receiving your letter dated January 31, 1996. Your letter helped us to clarify some of the issues that I have articulated in this letter. We look forward to working closely with you and the NRC on this project and we are anxious to keep our lines of communication open. In this regard, we have not received the information that Mr. Hawkins requested from you in his informal memorandum dated December 21, 1995 (copy enclosed).

Please contact me if you have any questions regarding the items requested at (301) 903-2105.

Sincerely,

Elaine K. Gallin

Elaine K. Gallin, Ph.D.
Deputy Director
Office of International
Health Programs

Enclosure

cc w/enclosure:
Al Rabson, NCI
Faye Austen, NCI
Andre Bouville, NCI
James Taylor, NRC
Shlomo Yaniv, NRC
Lynn Anspaugh, LLNL

Dose Reconstruction Program

(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

February 16, 1996

TO: Bruce Wachholz
Elaine Gallin
Ruth Neta
Mohandas Bhat
Shlomo Yaniv
Lynn Anspaugh

TELE NO:

FAX NO:

FROM: Sheilah Hendrickson

TELE NO: (510) 424-6410

SUBJECT: Equipment Status—Information and Update
(1) Equipment and Supplies—Belarus
(2) Equipment and Supplies—Ukraine
(3) Potential Problems
— Incremental shipments for IMX equipment
— Manpower curtailment

MESSAGE:

BELARUS—After speaking with Lynn during your January 24 trip to Minsk and in light of the temporary uncertainty of our project, and correspondence from Everett, I made the decision to stop shipments to Minsk. I have temporarily halted further purchases as well and have taken the following actions to minimize our cost (loss) should this project not go any further. Following is the current status of equipment with items of concern as noted. Comments and guidance are requested on the following:

We are transmitting 6 pages (including cover sheet)

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program
Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-453, Livermore, CA 94551-9900
University of California
Fax (510) 424-6408
Telex (910) 386-8339

1) DHL shipment (sitting in Customs since last November). I delayed and postponed the decision (return to LLNL or abandon) with DHL as long as I could. My last request was to provide DHL a decision upon completion of your January 24 meeting in Minsk. On January 30 LLNL again received a telephone call from DHL notifying us the package was still in Customs. I requested the shipment be returned to LLNL. This shipment is software/documentation for the dosimetrists and partial software for the computer for Alexander Ulanovsky. Shipment arrived back at LLNL, and it will be held here until further decision of project status.

2) Requested ComputerLand to redirect delivery location of computer and related software for dosimetrist (Alexander Ulanovsky) and to reroute delivery to LLNL rather than Minsk. Part of the order is currently in New Jersey, another part enroute to Minsk via Vienna. Both have been intercepted and are now being held at LLNL.

3) Medical patient file folders. Although Larisa Anspaugh spoke with Deputy Director Sviatelik for me as to whether these folders could be delivered to Minsk without further taxation (value added tax) to the Institute and without problems for removal from Customs to the Institute/Dispensary (he said he didn't think there would be a problem, if labeled medical and humanitarian aid), I have decided to continue to hold this item at LLNL since we have stopped all shipments and until status of our project is clarified. Although storage is an issue, I am attempting to locate and make "temporary" storage arrangements without any costs to us. We have 5,000 folders (6 pallets, approximately 3 tons). The cost of the folders was $9 K. Also, the shipment by air (2-3 week delivery) would cost $14 K; by water and land (8-12 week delivery) would cost $6 K. On the latter, we could include all items being held at LLNL, as we would have a transport container. Should our project in Belarus not move forward, my alternative suggestion is to use it for our project in Ukraine. This would require purchase of printed labels with special bonding adhesive (Approx. $1 K) to cover the printed logo of the Belarus project; there will be a small labor charge to put this label on the folders. Also, last December Dr. Mincey advised that there was no sign of the cohort being assembled in significant numbers.

4) Chemicals for urinary iodine determinations. We have finally "closed out" our chemical requisition/purchase order contract from last August. Vendors were not able to deliver arsenic, perchloric acid, or potassium chlorate. Only half of the cerium ammonium sulfate was delivered, and only by error (It is considered a hazardous chemical). These are considered hazardous chemicals and Customs in Minsk, Belarus, does not have an area to receive hazardous chemicals/materials. Everett has been working this issue since his August/September trip. He asked if we could find a truck-shipper to partial deliver if they balked at moving the entire order. However, I need DEFINITE direction otherwise I will run in to the same vendor/delivery problems. This may be a mute point depending on the outcome of our project. If the project continues and these chemicals are really needed, we may have to make an arrangement with a collaborating institute in East Germany. How urgent is the need for urinary iodine determinations?

5) Potential loss of "free use" of an IMX machine. An IMX machine was supplied "free of charge" in conjunction with our 1-year purchase contract for quarterly shipments of test kits. The IMX was delivered with 1/4 of the test kits. The second quarter shipment was due to be purchased and delivered last September. Per Everett, because the project was not operating as expected/planned, he requested us to delay this shipment to January 1996. We were successful at delaying the purchase and shipment again. The last and final delay has been extended until March. We are not fulfilling our part of the contract for purchasing test kits in exchange for the "free" use of the IMX machine. We have been notified that an order and delivery date must be given the first week in March or the IMX will be removed. If the IMX is removed (1) we will be put back on a waiting list for the next available machine (once we set up purchase and delivery again), and (2) we stand not to have a machine available for our use.

6) Shelf-life for Lyphocheck Immunoassay (freezed dried serum) expires in February 1996.

7) Shelf-life for Dyno Test Anti-TPO, Thyrax-Assay, Dyno Test Thyroglobulin (reagents for gamma counter) is 2 months or shorter. One hundred determinations/kits were delivered last on September 5, 1995.

8) Possible expiration of supplies/reagents to perform calcium and albumin assays for Kodak Analyzer. Do we need to be concerned?

9) Order of special technical software (3 programs) for Alexander (Oak Ridge Software Center) is pending. This is the software that requires DOE classification approval. Oak Ridge is taking care of this, however, they advise this could take from 3-months to 1-year for the approval. This process began the first of this month.

10) The following (in addition to what is mentioned above) are being held at LLNL for future shipments: multi-media drawers for the DCC, orbital mixer, platform for orbital mixer, 8 additional software with documentation (designated by Oak Ridge) for Alexander.

We also have "open-ended, on hold, or waiting for Sheilah to return to Minsk" items. Bruce, although you received on your last trip in 95 verbal information that "all" our equipment was supposedly exempted from custom duties and taxes, we agreed to test the system, but to no avail. When I tried to send the multi-media drawers at the end of the year, the Institute advised me to wait until we received exemption. Coupled with the update of the January 24 meeting, it is obvious this is also an item that is still unresolved. It is also unclear to me whether we will in the near future or ever have exemptions for office equipment and vehicles. As you are aware, we have been able to get around this issue by my purchase of office equipment and supplies from the local market.

11) Vehicles—Still waiting for exemption. If we ever receive the exemption, I will need to meet with vehicle dealers in Minsk. What was available last month, last week, or even yesterday, is not a guarantee the same is available today (limited stock on hand). We have not been very successful in telephone or fax requests for information and quotes. We have received bottom line quotes but have not received cost breakdowns. However, the information that we previously gathered is now outdated. I believe that once we receive exemptions we will need to ascertain what vehicles are readily available, and move quickly on the purchase order process. A possible alternative is the purchase of Russian-made vehicles, which we understand can be imported without duties. The previous Project Director rejected this proposal.

12) Office equipment—Still waiting for exemption. Sheilah to purchase in Minsk (company does not accept credit cards or purchase contracts) blinds, required material and supplies for Project Office. Per Everett, Deputy Director Sviatelik was to provide a list. In addition, Everett requested movable partitions.

13) Second ultrasound and associated equipment—On Hold. Will need specifications from Brill once we are a go with project. You mentioned prior to your January Minsk trip that we would probably need to get the Gomel site up and running quickly? Will this ultrasound be for Gomel and what other equipment will be necessary for Gomel?

14) Dedicated communication lines (2) between Dispensary and Institute. I will need to set up services on my next trip to Minsk. We previously agreed to temporarily pay the monthly rental until the RIRM received monies from the US. Will this change and does the Institute remember that they will pay this charge once they receive monies from U.S.?

15) E-mail services—I will need to set up something better than Lynn or I carrying cash to pay for services 4 months at a time. Next trip.

16) Computer for project office—I put this request from Everett from his previous trip on hold. There were computers in the DCC that were available and unassigned at that time.

17) RSA (Rose Systems) Medical laboratory software requested by Everett. This is information-management software across multiple disciplines (laboratory, AP, imaging, accounting, nursing etc.) Cost is approximately $5 K. On hold until resolution of project. Do we support the acquisition of software this expensive?

18) Unity PC Software (Bio Rad Lab) for Laboratory requested by Everett. This is interlaboratory quality control data management and reporting software. Cost is approximately $1.5 K. On hold until resolution of project.

19) HP scanner requested by Everett and Arthur. On hold. Unclear for necessity.

20) MOSCOW Dosimetrists. Office network. On hold pending resolution of project.

21) **Second Phase—On Hold Items**
- Second order of expendables
- Clinic files (unclear if medical patient file folders will only be used)
- Second order of Kodak, calcium/albumin slides/disposable tips
- Second air conditioner for dosimetry group
- Possible second shipment of paper for Moscow
- Cytopathology microscope—I think this should be completely deleted, correct?

UKRAINE

Bruce—I received from you on January 19, 1996 the equipment list for
- 3 pages for thyroid study
- 2 pages for leukemia study

Per your note, you requested I look at the list but also stated you have not OK'd anything, although it is likely. I would appreciate knowing where we are (timing) with these studies. Are the above lists the first phase or just a partial listing? There are several things I must have before I can even start the procurement and shipment process:

- At this time we have not received any money (or permission to use money on hand) for the leukemia project. And, of course, the protocol has not been signed. We will not begin purchases until we have clear instructions from DOE.
- Exemption of custom duty and tax letter from Ukraine for all equipment and supplies for thyroid, and leukemia studies.
- Do you know whether the US has an international agreement with Ukraine for Technical Assistance and Humanitarian Aid? This would be the same/similar as the copy I obtained between the US and Russia. I could check with NRC (Gordon Fowler) or Department of State (Carol Kessler), if you are unaware. Please advise.
- I will need to set up the databases
  - For each study for each participating institute/dispensary
- I will need to have written acceptance of my "acceptance and transference" of equipment and supplies procedures for each study:
  - Identify participating institutes /dispensaries/?
  - Identify who has overall equipment responsibility for study/location
  - Identify who has daily section responsibility at each location
  - Identify who I am to notify of shipments
  - Identify to whom and where shipments should be sent
  - Identify who has responsibility for proper paperwork as dictated by acceptance and transference procedures
  - Identify who will work with me for annual equipment audits
  - Name and title, address, telephone and fax number, e-mail address for all the above.

I will need to obtain additional information for some of the items on the equipment list that you faxed me. We will need to identify the items that can be purchased from their local market, ascertain the acceptance of credit cards or purchase contracts from LLNL, or based on the exemption of equipment whether it will be necessary for me to purchase items in person from their local market.

Because the Belarus project has not been fully operational in some areas and it is in temporary hiatus and because the Ukraine studies are not at a point of procuring equipment and supplies, it was necessary for me to drastically cut back support/time for one of my procurement coordinators. I have cut back support to 25% time and there is a real possibility that this procurement coordinator will not be available for our project(s) once we get the go-ahead. Should this happen it will take some time to find a replacement and bring this person up to speed. I would appreciate an update on where we are with these studies so I may plan accordingly.

Sheilah Hendrickson
Project Manager
FSU Equipment and Supplies

Dose Reconstruction Program

(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

March 28, 1996

TO: Bruce Wachholz
Elaine Gallin
Ruth Neta
Mohandas Bhat
Shlomo Yaniv

CC: The FRETTERS

TELE NO:

FAX NO:

FROM: Sheilah Hendrickson/Lynn Anspaugh

TELE NO: (510) 424-6409

SUBJECT: Necessary Actions Taken or To Be Taken Regarding Equipment and Supplies for Belarus and Ukraine

MESSAGE: Unfortunately, there has not been any response to the fax (copy follows) sent on February 16, 1996, to the above-named addressees. The prior fax contained urgent requests for decisions to be made concerning our operations in ordering and delivering equipment and supplies for the BelAm and UkrAm Thyroid Projects. This lack of response has been very disconcerting, and, in fact, the passage of time has already caused some decisions to be made for us. And, unfortunately, we are sure that some members of the FRETTERS will be very distressed that this lack of decision-making has precluded, at least temporarily, the ability of the BelAm Thyroid Project to make some kinds of measurements with any assurance of quality.

We are transmitting 10 pages (including cover sheet).

Further, everyone should know that the amount of money allocated to LLNL for "administration and coordination" has been cut in half, and we have already made significant reductions in our staffing for the purchasing and shipping of equipment and supplies. DOE has given us enough flexibility so that we can probably continue to perform the essential purchasing functions at the expense of money allocated for science, but we no longer have the money, the time, or the energy to beg and wheedle NCI to make decisions. Thus, unless we hear immediately, the purpose of the present fax is simply to inform you of what decisions have already been made for us by the passage of time and of what decisions we at LLNL are making immediately in lieu of receiving any response from NCI.

We at LLNL are also concerned that we have not been included in recent FRETTERS meetings, like the one in New York City, and we have not been included in recent conference calls that ostensibly had been scheduled to include all of the FRETTERS. Thus, while some of you may have made decisions in conflict with those indicated below, we have no such knowledge.

BELARUS

We are in the process of sending a letter to Dr. Viktor Sviatelik to indicate what material we intend to ship in the near future. The purpose of such a letter is to allow him to make sure that exemptions, etc., will be in place. And, of course, any actual shipment will be delayed until we have a positive response on the requirements of the funding arrangement. The materials to be included in the next shipment would be the medical patient folders, the orbital mixer, the computer system for Ulanovsky, and all other materials being held at LLNL. One needed decision was whether to ship these materials by air (2–3 weeks delivery) or by land and sea (8–12 weeks delivery). As the cost is more than twice to ship by air ($14,000), we have decided to ship by land and sea.

We had not been able to ship all the chemicals that we had purchased for urinary iodine determinations, as some of these chemicals are considered hazardous. We were told that Mincey would work to solve this problem for us following his August/September trip, but no information has been received. We had asked the question of how urgent is the need for urinary iodine determinations in Sheilah's prior fax. In the absence of any response, Lynn has decided that urinary iodine determinations are beyond the primary scope of the project, and we will make no further efforts to deliver such chemicals.

A more serious question involves the IMX analyzer to be used for clinical chemistry determinations. The problem was that we have not, due to

Mincey's instructions, fulfilled our contract for quarterly shipments of test kits. The first quarter's kits were delivered with the machine in June 1995. The September shipment was delayed until January. Mincey again requested that this shipment be delayed until March. We were told by the vendor that, if the order was not placed for a delivery date during the first week of March, that the IMX machine would be removed. Unfortunately, there was no response for our urgent request for a clarification on this issue, and the passage of time has made this decision for us. We presume that this machine has either been removed already or will be in the near future; and we have no assurance that we can readily get such a machine again. In addition, the IMX kits and many of the other chemicals that had been ordered and delivered during September 1995 have a limited shelf life. We presume that none of these chemicals can be used for any reliable, quality-assured determinations. In the absence of any clear instructions, Lynn has decided that clinical chemistry is also beyond the primary scope of this project, and LLNL is dropping the matter.

Expensive (about $6,500) software had been requested by Mincey for clinical laboratory use. We had asked, if the purchase of this equipment was supported by NCI. As there was no answer, and as no one seems to be interested any longer in clinical chemistry, this software will not be purchased.

We had been informed previously that we should be prepared to equip the Gomel Dispensary soon. As work in the Minsk Dispensary has not yet been started, we don't see any point in starting to equip a facility in Gomel. Unless we receive information otherwise, we will not consider the purchase of any equipment for Gomel at this time. If such equipment is needed in the future, we will need an approved list.

UKRAINE

We had received from Wachholz on January 19, 1996, two equipment lists (one addressed to Wachholz from Tronko dated December 7, 1995; another addressed to Brill from Epstein dated November 20, 1995). We have just recently received (March 27, 1996) another composite list from Dr. Brill that he accumulated during the January visit. We did not previously know about this list, but had assumed that the only lists available were those given to us by Wachholz on January 19.

During the March meeting with the Ukrainian team Lynn indicated that some lists of equipment and supplies had been received at LLNL, but that there was no evidence that they had been approved by Wachholz. Wachholz indicated that he had never seen any list; such reference must have been to the list just now forwarded from Brill, as the original lists we had in our possession came from

Wachholz. Lynn further stated that no equipment would be ordered by LLNL unless there was evidence of some formal process of approval with direct approval by both Tronko and Wachholz.

Such comments have stirred up the Ukrainians to a significant extent. We understand that they have been having meetings starting this week among all participants (including dosimetrists) in the Thyroid Project, and that a new comprehensive list will be forthcoming.

We at LLNL have been anticipating that there would be an orderly process to define the priorities for the purchase of equipment for the UkrAm Thyroid Project, and that this process would be similar to that used for the BelAm Thyroid Project. Lynn's memory is that this process involved several meetings of the FRETTERS for this purpose and that these meetings included one or more individuals from Belarus. Thus, it seems most irregular that almost one year after the UkrAm Thyroid Protocol was signed that there is no evidence of such a process, even though there have been several "management" trips to Ukraine during which such matters were presumably discussed. We know that Dr. Brill has accumulated lists of equipment, but we presume that these wish lists will need substantial pruning by the entire group of FRETTERS before we can proceed. There is almost certainly not enough money to purchase everything on the lists submitted or to be submitted by the Ukrainians.

The situation in Ukraine is particularly important in our view, as there is $500,000 within our system that originated from the NRC; this money was specifically designated for equipment and supplies for the UkrAm Thyroid Project. We don't know if there is a problem with this money disappearing at the end of the fiscal year, and we ask that those concerned (Yaniv and Gallin) look into this. It does not seem at all likely that this money can be spent wisely within the remaining months of this fiscal year. However, it is long past time for the process to begin.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of He
National Cancer Institute
Bethesda, Maryland 208

April 5, 1996

Elaine K. Gallin, Ph.D.
Deputy Director
Office of International Health Programs
U.S. Department of Energy
Germantown, MD 20874-1290

Dear Dr. Gallin:

Following my return, I received a letter from Dr. Randy Brill with a list of equipment requested by Dr. Tronko and his staff for the Ukraine thyroid project. This is not a complete list but is what they call their priority list, consisting primarily of diagnostic and pathology needs. He had held it pending reinstatement of the procurement process. A second list, including equipment also for a Data Coordinating Center, a central laboratory and dosimetry, was received today from Dr. Tronko.

While a number of items and issues regarding specifics will need to be resolved with Dr. Tronko and/or his colleagues, there are at least two alternative ways of proceeding on this matter and your guidance would be appreciated. We could (1) follow the Belarusian precedent and begin to request LLNL staff to procure the equipment and ship it to Ukraine as soon as possible, even if prior to reaching bilateral agreement on programmatic, reporting and funding issues, or (2) defer procurement and shipment until the details of the project have been worked out, i.e. tasks, milestones, man-months, etc., the funding arrangements negotiated and signed before initiating equipment purchase requests. Of course, exemption from custom taxes, etc. would need to be obtained before either option is implemented. Efforts to obtain information regarding availability and cost could be initiated at any time, however, subject to time and effort convenience at LLNL.

Similar guidance regarding Belarus also would be helpful. Do you prefer that procurement and shipment of additional equipment and supplies be deferred until the Belarusian government approves and identifies resources, however limited, for this project as a state project, and until other DOE requests are complied with and U.S. funds are transferred?

Our administrators remind me that we soon will exhaust funds for Chornobyl-related activities. The $85,000 from DOE that we were permitted to use from FY 1995 and the matching NCI monies are expected to cover our activities through the end of April or early May.

We hope that the $165,000 that was to be transferred to NCI can be located so that the $50,000 can be made available for Belarus and $115,000 can be transferred to NCI to permit us to continue activities without interruption.

Dr. Masnyk and I look forward to hearing from you regarding these matters.

Sincerely,

for Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

April 8, 1996

Ms. Sheilah Hendrickson
University of California
Lawrence Livermore National laboratory
P O. Box 808, L-453
Livermore, CA 94551-9900

Dear Ms. Hendrickson:

Dr. Wachholz left for Vienna last Sunday night. In his absence I would like to thank you for your memorandum of April 4, with the appended list of desired equipment from Drs. Tronko and Likhtarev.

We have also received the same equipment needs directly from Dr. Tronko; his cover letter is enclosed. The only difference, as we see it, is that it is called "Priority Equipment and Supply" list. We wonder about the meaning of this. Dr. Wachholz plans to discuss this with Dr. Tronko in Vienna. When we get a better reading, we will forward to you proper approval to begin the purchase of items requested.

In addition, Dr. Tronko provided preliminary suggestions for tasks, which Dr. Wachholz also plans to discuss with him. When both sides reach agreement, this will be distributed as appropriate.

We discussed the issue of IMX with some of our advisors. It does not seem to be such a big problem as you perceive it. However, we are working on a detailed reply to your memoranda from the 16 and 28 March and we will address the resolution of the IMX problem, if any, at that time.

Thank you again for your timely communications.

Sincerely,

Ihor J. Masnyk, Ph.D.

Attachments

cc: Dr. E. Gallin
Dr. S. Yaniv

Department of Energy
Germantown, MD 20874-1290

APR 12 1996

Dr. Bruce W. Wachholz
Radiation Effects Branch
National Cancer Institute
9000 Rockville Pike, EPN 530
Bethesda, MD 20892

Dear Dr. Wachholz:

Thank you for your memorandum updating me on items of interest that occurred following my departure from Minsk on March 20, 1996. In response to your letter of April 5, 1996, requesting guidance and/or information on several issues:

1) With regard to your inquiry about the fiscal year (FY) 1996 DOE funds that we committed to transfer to the National Cancer Institute (NCI) to support the Chernobyl-related studies that we are cofunding, we processed the Work Authorization to send you an additional $115,000 for FY 1996 in mid-March shortly after our meeting at the Nuclear Regulatory Commission (NRC). Together with the $85,000 of carryover funds from last year, the total Department of Energy (DOE) funds contributed in FY 1996 as part of the 1992 Interagency Agreement between the NCI and DOE is $200,000. Shortly after receiving your letter, Ann Ecton faxed you a copy of the Work Authorization that we submitted. You should be receiving those funds in mid-April. If you have not received them in the next week or so, please contact Ms. Ecton (903-3889) so that she can track the paperwork.

2) With regard to equipment and supplies for the Ukrainian Thyroid Study, we have discussed the situation with Lynn Anspaugh and Sheila Hendrickson at the Lawrence Livermore National Laboratory (LLNL). DOE has agreed that LLNL would begin to put the process in place to procure and ship equipment and supplies to Ukraine. As you know from the fax that you received on February 16, 1996, from Sheila requesting your assistance on a variety of issues, there are a number of administrative details that need to be worked out. Sheila will be contacting you to resolve those details. This process is likely to take 4 to 8 weeks at a minimum. We hope that the U.S. team can work together with the Ukrainian scientists to reach bilateral agreement on programmatic, reporting, and funding issues in that time period.

3) With regard to the equipment and supplies for Belarus Thyroid Study, we believe that it is important to continue the momentum that we gained by signing of the Funding Arrangement in March. Thus, we have told Sheila to proceed with the transfer of the equipment and supplies for the Belarus Project. It is our hope that the Funding Arrangement will be implemented in the very near future.

Printed with soy ink on recycled paper

In addition to your requests, we have received copies of several faxes from Sheila Hendrickson's dated February 16, March 28, and April 4, as well as a copy of her letter to Dr. Ihor Masnyck dated April 12, 1996, (enclosed) that indicate that the LLNL is not getting the support that they need from the NCI or from Olga Tsvetkova. This is an issue of considerable concern to all of us. We would like to arrange for a meeting to discuss some of the issues raised in Sheila's correspondence. Additionally, we would very much like to understand that process that you as the manager of these projects have put in place with the Scientific Working Group to review and finalize the list of equipment and supplies required for these projects. It would be very helpful for us if the meeting scheduled to discuss the issues of concern to LLNL also included a discussion of this process. We will be in contact with you and the NRC to schedule the meeting.

Finally, I am enclosing a copy of a letter that I received from Dr. Nikoly Tronko last week, along with my letter of response. Please note that I told Dr. Tronko that you or a member of the U.S. Scientific Working Group would contact him regarding the 3-month milestones and the dosimetry personnel changes that he included in his letter. We would appreciate being kept updated on this matter.

Please let Mr. Frank Hawkins or I know if you have any questions about the issues for which you requested our guidance, or any other issues that I have discussed in this letter.

Sincerely,

Elaine K. Gallin

Elaine K. Gallin, Ph.D.
Deputy Director
Office of International
Health Programs

Enclosures

Dose Reconstruction Program

(Former Risk Sciences Center)

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(510) 424-6410
hendrickson3@llnl.gov

April 12, 1996

Dear Ihor:

Thank you for your April 8 fax letter.

We, too, received a copy of the letter to Bruce from Dr. Tronko. We do appreciate your willingness to share it. We have also received a copy of Drs. Tronko and Likhtarev's April 2, 1996, letter to Dr. Elaine Gallin and are sending a copy for your and Bruce's information.

In your 4th paragraph you state that a detailed reply to my memoranda of 16 and 28 March is being prepared. Just to clarify, I believe you meant to say February 16 and March 28. (You neglected to mention the e-mail message to Bouville and Wachholz dated March 30.) It is also mentioned in this same paragraph that the IMX does not seem to be such a big problem as I perceive it. Well we agree that the IMX is not a problem for those not involved in the process. On the other hand, it is a very real problem for those of us holding an unfulfilled contract with Abbott which includes making 4 quarterly purchases in exchange for "free" use of the IMX. At this time the 4th quarter purchase should have already been placed and it is still unknown, if and when, the 2nd quarter purchase will indeed be placed. We also have been informed by Abbott that we can no longer hold them to the quoted contract price because we have not fulfilled our part of the contract. If the machine is lost from Minsk, then NCI can take over this job and find out how big a problem you perceive it to be. As stated previously, we do not intend to perform our job more than once due to NCI not providing timely decisions or project guidance.

We are glad to hear that Bruce will be discussing several issues with Dr. Tronko including the equipment list. During my first trip to Ukraine last June I brought up the issue of exemption of custom duties and taxes and Ogla Tsvetkova stated there wouldn't be any problems. Upon my return this was also mentioned to Bruce and noted to both that I needed something in writing from Ukraine. However, to date, I have received nothing. During this same trip I also had preliminary equipment discussions with Drs. Romanenko and Tereshchenko (Dr. Tronko requested I work with his Deputy since he was leaving on travel) regarding the process of transference and acceptance of equipment. During the meeting between Dr. Romanenko and the Americans, Olga Tsvetkova agreed to translate my "draft" transference and acceptance of equipment procedures for Drs. Romanenko and Tereshchenko. Please verify whether Drs. Romanenko, Tereshchenko or Tronko

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Atmospheric and Ecological Sciences Program
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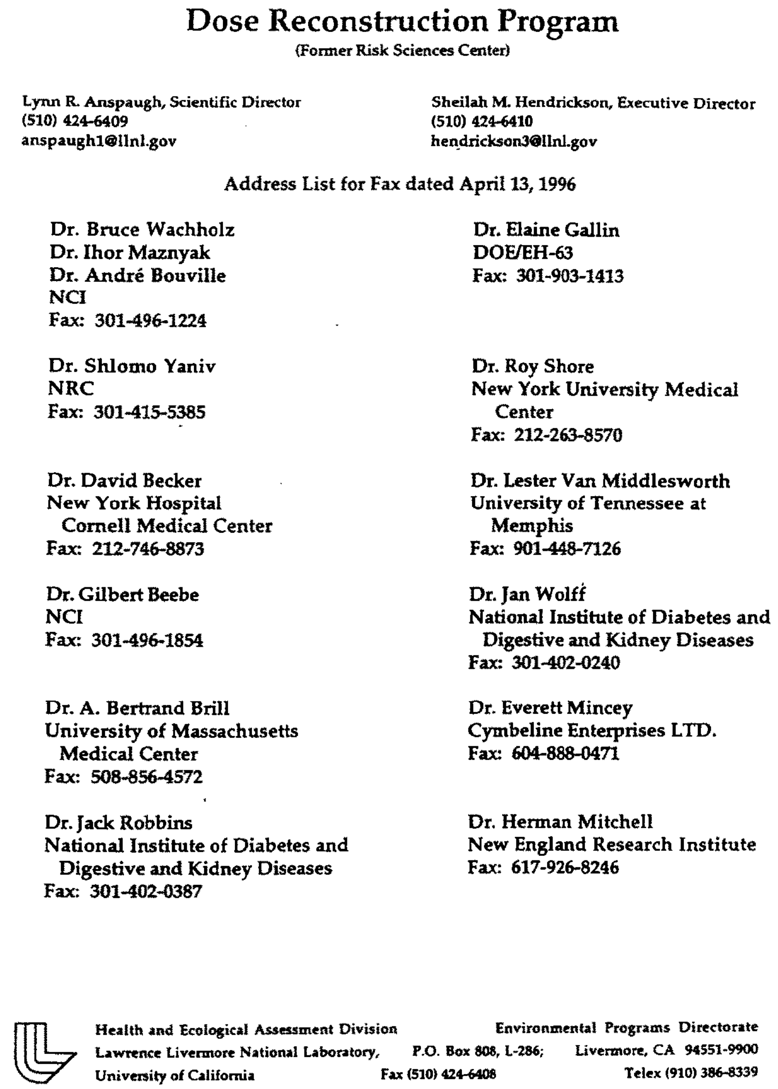
received such a translation. An English version was left with each of them. As you are aware, because I have not received any comments or guidance from Bruce regarding my February 16 fax, we are not in a position to start the purchase and shipment of equipment to Ukraine. If, as we fear, NCI has failed to take care of this matter, we can deal directly with the Ukrainian authorities to solve this problem.

Your letter mentioned some concerns and clarification needed concerning the consolidated list of equipment received from Tronko. As this list is the direct result of our (LLNL) initiative, we can provide any needed clarification. This is the list of equipment the Ukrainians feel they need to get the project underway. The list is shorter than expected, but the Ukrainians remind us that the list in the "Protocol" was prepared many years ago, and there was no attempt to put a lid on the wishes. Since then, the Europeans have purchased a lot of equipment, and this equipment can be shared by this Project. Also, we were very blunt in telling them that the money for equipment and supplies was limited to $500,000.

We have had and will continue to have discussions with DOE and NRC on how we can proceed to get this project moving in the absence of any direction from NCI. In the near future we will proceed to purchase equipment from the Ukrainian list according to our best judgment and that of our sponsors and advisors. We are no longer willing to accept a "do nothing, no response" attitude from NCI.

Sheilah Hendrickson

Sheilah Hendrickson
Project Manager
Equipment and Supplies



Dose Reconstruction Program

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Address List for Fax dated April 13, 1996

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Dr. André Bouville
NCI
Fax: 301-496-1224

Dr. Shlomo Yaniv
NRC
Fax: 301-415-5385

Dr. David Becker
New York Hospital
Cornell Medical Center
Fax: 212-746-8873

Dr. Gilbert Beebe
NCI
Fax: 301-496-1854

Dr. A. Bertrand Brill
University of Massachusetts
Medical Center
Fax: 508-856-4572

Dr. Jack Robbins
National Institute of Diabetes and
Digestive and Kidney Diseases
Fax: 301-402-0387

Dr. Elaine Gallin
DOE/EH-63
Fax: 301-903-1413

Dr. Roy Shore
New York University Medical
Center
Fax: 212-263-8570

Dr. Lester Van Middlesworth
University of Tennessee at
Memphis
Fax: 901-448-7126

Dr. Jan Wolff
National Institute of Diabetes and
Digestive and Kidney Diseases
Fax: 301-402-0240

Dr. Everett Mincey
Cymbeline Enterprises LTD.
Fax: 604-888-0471

Dr. Herman Mitchell
New England Research Institute
Fax: 617-926-8246

Health and Ecological Assessment Division Environmental Programs Directorate
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April 13, 1996

TO: Those on Preceding List

TELE NO:

FAX NO:

FROM: Lynn Anspaugh

TELE NO: (510) 424-6409

SUBJECT: More on Ukrainian Thyroid Study

MESSAGE: As part of our continuing effort to get this project moving (note that May 10 will be the one-year anniversary of the signing of the agreement), we have had several conversations with the thyroid worker bees in Ukraine.

They take very unkindly to the idea that yet another American delegation will come to Ukraine to discuss the equipment list. It seems that they are all telling American jokes over there regarding our penchant for all talk and no action. They suggest that they can answer any questions either directly by telephone or by fax; yes, they can read English and they have people (both in Tronko's and Likhtarev's Institutes) who can speak English. If we don't have NCI approval within one week, we will petition DOE and NRC for their approval so that we can *do something.*

It is now obvious that some members of our American team are trying to hold the thyroid and the dosimetry-research studies hostage until the leukemia study can catch up. However, this seems blatantly unfair, especially to the 452 children in Ukraine who already had thyroid cancer through 1995 and to the hundreds or even thousands who may get it in the future. It is time to move aggressively to select the cohort and to facilitate the screening portion of our study. Otherwise, there may never be an academic portion. Hopefully, we will be able to screen some of these "children" before they all die of old age, if not thyroid cancer.

We are transmitting 4 pages (including cover sheets).

Enclosure: Fax to Tronko dated April 13, 1996

Health and Ecological Assessment Division   Environmental Programs Directorate
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Dose Reconstruction Program

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hendrickson3@llnl.gov

April 13, 1996

TO: Nikolai Tronko

TELE NO:

FAX NO: 380-44-430-37-18

FROM: Lynn Anspaugh

TELE NO: (510) 424-6409

SUBJECT: U.S.-Ukraine Agreement on Thyroid-Cancer Studies

MESSAGE: During recent conversations with you or one of your staff members, it was indicated that you do not have a signed copy of the agreement concluded on May 10, 1995, by the U.S. and Ukrainian authorities on the Thyroid-Cancer Studies.

A copy of this agreement follows. I apologize that this copy is not very good, as it had already been faxed three times when we received it. We will try to get you a better copy in due time.

We hope the copy of this agreement will be of assistance to you in ensuring that equipment to be shipped to Ukraine will be exempt from any customs or taxes. Now that we have received your consolidated list of requested equipment, we will be doing our best to see that the list receives appropriate, prompt approval so that purchase and shipment can begin.

Also, we would like to know whether you or Dr. Tereshchenko have received a copy of our draft procedures for transference and acceptance of equipment; these materials were discussed with your staff during the visit of Ms. Hendrickson to your institute last year. We understood that these procedures were to have been translated and delivered to you by Dr. Tsvetkova. If you don't have them, we will fax them directly to you. Even though we have them only in English, we trust that they will be useful.

Best regards from all of us,

We are transmitting 2 pages (including cover sheet).

Health and Ecological Assessment Division Environmental Programs Directorate
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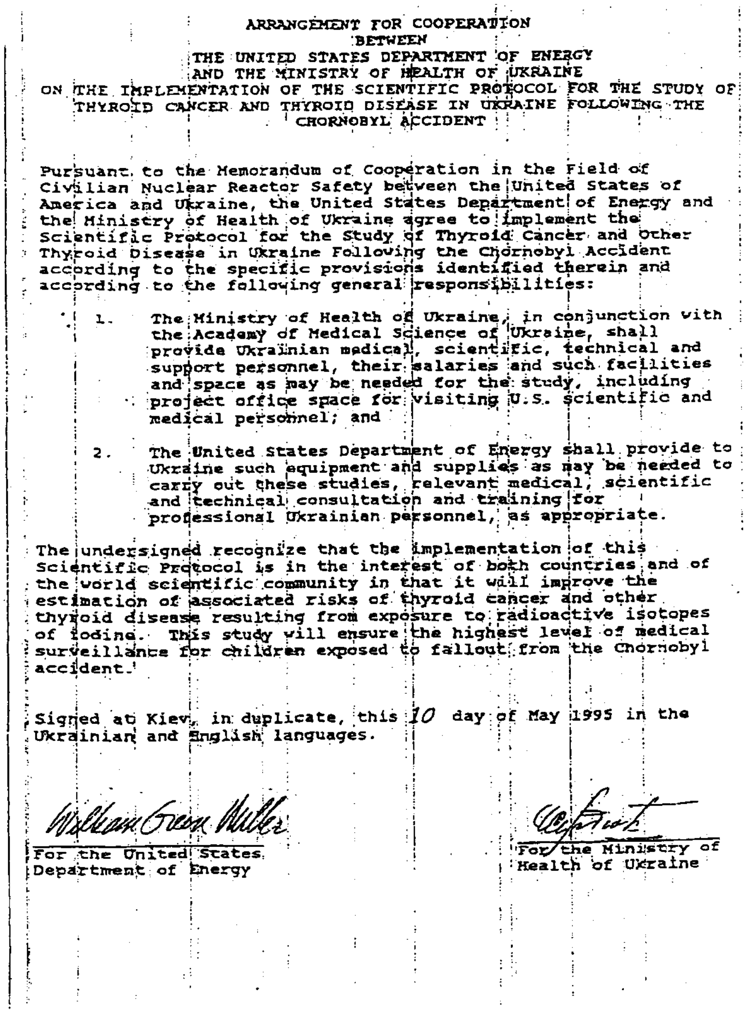


ARRANGEMENT FOR COOPERATION
BETWEEN
THE UNITED STATES DEPARTMENT OF ENERGY
AND THE MINISTRY OF HEALTH OF UKRAINE
ON THE IMPLEMENTATION OF THE SCIENTIFIC PROTOCOL FOR THE STUDY OF
THYROID CANCER AND THYROID DISEASE IN UKRAINE FOLLOWING THE
CHORNOBYL ACCIDENT

Pursuant to the Memorandum of Cooperation in the Field of Civilian Nuclear Reactor Safety between the United States of America and Ukraine, the United States Department of Energy and the Ministry of Health of Ukraine agree to implement the Scientific Protocol for the Study of Thyroid Cancer and Other Thyroid Disease in Ukraine Following the Chornobyl Accident according to the specific provisions identified therein and according to the following general responsibilities:

1. The Ministry of Health of Ukraine, in conjunction with the Academy of Medical Science of Ukraine, shall provide Ukrainian medical, scientific, technical and support personnel, their salaries and such facilities and space as may be needed for the study, including project office space for visiting U.S. scientific and medical personnel; and

2. The United States Department of Energy shall provide to Ukraine such equipment and supplies as may be needed to carry out these studies, relevant medical, scientific and technical consultation and training for professional Ukrainian personnel, as appropriate.

The undersigned recognize that the implementation of this Scientific Protocol is in the interest of both countries and of the world scientific community in that it will improve the estimation of associated risks of thyroid cancer and other thyroid disease resulting from exposure to radioactive isotopes of iodine. This study will ensure the highest level of medical surveillance for children exposed to fallout from the Chornobyl accident.

Signed at Kiev, in duplicate, this 10 day of May 1995 in the Ukrainian and English languages.

William Green Miller
For the United States
Department of Energy

For the Ministry of
Health of Ukraine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

April 15, 1996

Ms. Sheilah Hendrickson
Lawrence Livermore National Laboratory
University of California
P.O. Box 808, L-453
Livermore, CA 94551-9900

Dear Sheilah:

Following are our comments to your FAX messages to me dated March 28 and February 16, 1996 and to Dr. Masnyk dated April 12, 1996. The January 24 meeting in Minsk left us uncertain in respect to the future of our project because of the unresolved issues of the financial support for "local assistance." Then your memorandum of February 16, 1996 was interpreted as a fait accompli which required no input from NCI. At this time, however, we feel it is necessary to address all the points raised by you to clear up possible misunderstandings on both your and our side to avoid rushed unilateral actions in the future.

Re: FAX dated March 28, 1996:

Your first paragraph on page 2 refers to some of your decisions re contractual relationship with DOE, which surprised us ("swapping" science dollars for administrative expenses) and caught us unaware of your budgetary cuts. If the present material is insufficiently immediate, we should hope that unilateral decisions made at LLNL are not necessarily irrevocable and, in light of the progress in Minsk during the March 20 agreement, could be modified.

Concerning the FRETTERS meetings: the last FRETTERS meeting was held over a year ago. All members, including a DOE observer, were invited. Since that time there have been no FRETTERS meetings; certainly we are unaware of a New York FRETTERS meeting having taken place. Several members of our group met with Dr. Cherniack in Dr. Becker's office in March 95 to discuss his role in the NCI program but that was not a FRETTERS meeting. There was a recent telephone conference call involving several members of the FRETTERS and DOE (Dr. Gallin); this also concerned a personnel matter relating to Dr. Brill's proposal with respect to Mr. Kuvshinnikov and was not a FRETTERS conference call.

Regarding the first paragraph under the subtitle Belarus, we certainly are in agreement and appreciate the LLNL decision not to ship by air.

Next paragraph: iodine determinations are not urgently needed at present, but were specifically requested by Belarus and Ukraine and are an essential protocol item that we must respect. Equipment to support these determinations and some chemical supplies have already been sent to Minsk. The only problem is the difficulty with the reagents considered hazardous, especially when shipped by air. We understand that Dr. Mincey discussed this with you and recommended the use of truck delivery overland from Germany. This is an issue which may require some imaginative solution rather than unilateral cancellation.

An IMX analyzer or its equivalent also is essential to the project. One was sent to Minsk with an initial batch of required reagents for T-4, FT-4 and TSH analysis under a reagent-use agreement. It was done in connection with the projected development of a study cohort which unfortunately has not materialized. Cohort selection has been delayed by factors beyond our control. Without patients, maintaining proper inventory of limited shelf-life reagents would, as you point out, be too expensive. If Abbott wants to take it back, we should return it and renegotiate a new agreement at the time when we will have cohort members in the pipeline; we understand that Abbott is usually quite understanding when such problems are explained to them. We are in strong disagreement with Dr. Anspaugh's opinion that clinical chemistry is beyond the scope of this project, since its inclusion was insisted upon by Belarussian and Ukrainian colleagues and, as such, is an integral and vital part of the study.

It seems reasonable to us that requests for software for the clinical laboratory should be put temporarily on hold.

We agree with you on the Gomel issue. The Gomel examining station will eventually become more important than the Minsk site in terms of patient accrual, but we cannot certify the equipment and supplies for Gomel until (a) Minsk has started its operations and (b) we have surveyed the needs for Gomel operations in detail.

Re: first paragraph under subtitle Ukraine, Dr. Masnyk sent you a memo on April 9 concerning Dr. Tronko's equipment request. I intend to discuss it in detail with Dr. Tronko during my trip to Vienna and Kiev. The initial list of equipment was sent to you in January, following extended furloughs here in Washington. The next iteration of equipment was received from Dr. Brill in late March; you and we received it simultaneously. Similarly, you and we received the most recent list of equipment from Dr. Tronko; unfortunately, this list still is not complete, e.g., with respect to the Data Coordinating Center. We feel it is essential for us to consider the totality of equipment and supplies needed to get the project started and to do so in light of the funds available for Ukraine. We expect to visit Kiev in May for this purpose.

We agree that it would be inappropriate for LLNL to initiate purchases without NCI approval. NCI will negotiate lists of equipment and supplies with those responsible for the work in Belarus and Ukraine. The requests for purchase should be channeled through me or my designee for approval without which there should be no action. This does no preclude others advising LLNL on technical specifications.

The outlook for the thyroid project in Ukraine has been, and remains, uncertain, pending an agreement on "local assistance" or some other form of commitment by DOE. Based on the signing of such an agreement with Belarus on March 20 we believe that the prospects for the parallel study in Ukraine are sufficiently promising for consideration to be given to its supply and equipment needs. We propose to organize this effort promptly, and again, with regard to the funds available.

It is our understanding, based on a telephone conversation between Dr. Beebe and Dr. Yaniv, that the NRC can permit its funds to be expended in FY97 and we assume that it will do so. As indicated above, we too, are sensitive to the relation between the money available and the estimated cost of what the Ukrainian project seems to need.

Re: FAX dated February 16, 1996:

Some of the points raised by you in this FAX have already been answered above; I will refer to them as appropriate. The other items will be answered using your numbering system.

Items 1, 2, 3 have been already handled by you; we agree with your course of action.

Items 4,5 were discussed above.

Items 6-8: we did not expect the project to get stalled pending resolution of local support. All of these items were purchased in small lots. Some have already been used to calibrate and standardize instruments. For the time being we should not reorder until there is a real cohort for testing and the number of patients per week can be established.

Item 9: no comment.

Item 10: the issue of exemption from custom duties and taxes was inserted in the funding agreement signed March 20, 1996 in Minsk. We expect the Belarussians to make certain that this will be so. Until this is achieved, DOE's agreement could not be implemented. There is little NCI can do, except to remind Dr. Krisenko about this requirement, and we will do so.

Item 11: several individuals seem to be actively interested in this topic and each tries to solve it in his own way without necessarily coordinating with others. This topic needs to be re-addressed, looking possibly for new solutions.

Item 12: keeping in mind that RIRM may move to a new location, we should wait until we know for sure which offices will require what equipment.

Item 13: Gomel site requirements were discussed above.

Items 14,15: the new DOE financial agreement signed March 20 provides 10% of local support to be spent on such services.

Items 16-18: I agree. All of these can be postponed for the time-being. They will be needed when the laboratory in Belarus will be operational.

Item 19: it seems like a good idea to have one HP scanner for the entire project. It should be located at the DCC.

Items 20,21: now that the decision to go ahead with the project has been made, tne Moscow dosimetrists' needs should be addressed. The AC should be sent and the paper for Moscow as well. I agree with your decision on other items; and finally, the microscope should be deleted.

Concerning Ukrainian projects, as you know, we have just received a priority list for equipment and projected man-month requirements for Dr. Tronko. It needs to be discussed in greater detail, which I will attempt to undertake on my current trip. A small group of FRETTERS will be sent to Kiev soon to go over all the details, building on our experience in Belarus. Further, I expect guidance from DOE regarding the timing for procurement of equipment and supplies. The thyroid project could be launched as soon as the financial agreement is achieved between Ukraine and DOE. We will work on all the specific details (customs exemptions, individuals responsible for various administrative tasks, etc). The leukemia study probably will be running 3-6 months behind the thyroid project. Again as we handle the necessary details, we will keep you informed.

Re: Fax dated April 12, 1996:

Thank you for sending a copy of Dr. Tronko and Liktarev's letter of April 2, 1996 to Dr. Elaine Gallin; we had already received a copy of it, but keeping each other informed is a step in a positive direction.

The reference to the IMX and the problems associated therewith in no way was intended to reflect on the level of effort required by you to prepare and execute the contractual requirements. As I understand the exchange, the reference to the "problem" was wheather or not Abbott might be willing to reconsider a similar IMX loan arrangement in the future. Our colleagues who have interacted with Abbott in the past are of the opinion that this is unlikely to be a problem; they might also be willing to assist you (if you wish) in future discussions with Abbott. I regret any misunderstanding when our reference was to a future problem with Abbott, whereas from the tone of your paragraph you interpreted the comment as being a reflection on the contractual effort needed to make the arrangements; the latter clearly is a non-trivial issue.

When I discussed with Dr. Tronko the issue of tax exemptions, acceptance, accountability and responsibility, etc. for equipment, he merely stated that Dr. Tereshchenko would need to look into these items. I did not recall or had forgotten that you had left documents with them for translation. This will be raised in Kiev next week.

You suggest that we should not discuss "concerns and clarifications" regarding equipment with the Ukrainians, but rather that these matters should be discussed with you. However, not being aware that you had established such a policy, I did discuss some of these issues with Dr. Tronko, the immediate result of which was to eliminate one $20,000 item from the list. It may be that other adjustments also can be made that might reduce costs to the U.S. government.

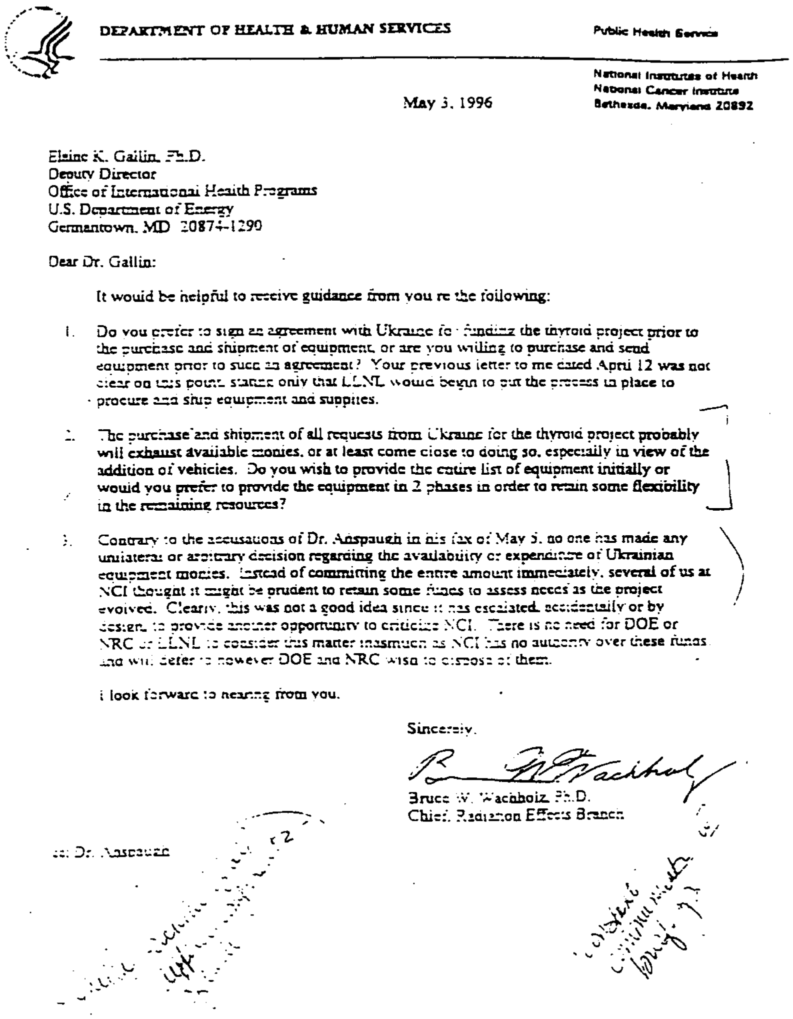
Your final two paragraphs seem to imply that you intend to assume all responsibility for equipment and supplies. That clearly is your and DOE's prerogative. As I'm sure you're aware, DOE is drafting a new interagency agreement between DOE and NCI; this also might be an appropriate vehicle to clarify the relationships between NCI and DOE support contractors.

It is regrettable that you and your colleagues have chosen to express yourselves with intemperate language within the past few months, whereas for the past thirteen years NCI and LLNL have enjoyed a most amicable, cooperative and mutually supportive and productive relationship including everything from technical matters to personnel issues. (On a personal level, the relationship goes back twenty or more years.) I would hope that the current apparent stresses are a temporary aberration.

I hope this cleans our slate. We look forward towards a delay-free period from now on.

Sincerely,

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

May 3, 1996

Elaine K. Gallin, Ph.D.
Deputy Director
Office of International Health Programs
U.S. Department of Energy
Germantown, MD 20874-1290

Dear Dr. Gallin:

It would be helpful to receive guidance from you re the following:

1. Do you prefer to sign an agreement with Ukraine for funding the thyroid project prior to the purchase and shipment of equipment, or are you willing to purchase and send equipment prior to such an agreement? Your previous letter to me dated April 12 was not clear on this point, stating only that LLNL would begin to put the process in place to procure and ship equipment and supplies.

2. The purchase and shipment of all requests from Ukraine for the thyroid project probably will exhaust available monies, or at least come close to doing so, especially in view of the addition of vehicles. Do you wish to provide the entire list of equipment initially or would you prefer to provide the equipment in 2 phases in order to retain some flexibility in the remaining resources?

3. Contrary to the accusations of Dr. Anspaugh in his fax of May 3, no one has made any unilateral or arbitrary decision regarding the availability or expenditure of Ukrainian equipment monies. Instead of committing the entire amount immediately, several of us at NCI thought it might be prudent to retain some funds to assess needs as the project evolved. Clearly, this was not a good idea since it has escalated, accidentally or by design, to provide another opportunity to criticize NCI. There is no need for DOE or NRC or LLNL to consider this matter inasmuch as NCI has no authority over these funds and will defer to however DOE and NRC wish to dispose of them.

I look forward to hearing from you.

Sincerely,

B W Wachholz

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

cc: Dr. Anspaugh

Department of Energy
Germantown, MD 20874-1290

MAY 10 1996

Dr. Bruce Wachholz
Chief, Radiation Effects Branch
National Cancer Institute
6130 Executive Boulevard, Rm. 530
Rockville, Maryland 20852-7391

Dear Dr. Wachholz:

I am writing in response to your letter dated May 3, 1996.

1. Purchase and shipment of equipment and supplies for Ukraine We had hoped that the process of purchasing and shipping equipment and supplies to Ukraine would have begun months ago. This process does not have to wait for the supplementary Funding Arrangement to be put in place, since we have a signed protocol in place. Thus, we would greatly appreciate if you could work with the scientific working group to finalize the equipment and supply list, and to ensure that the process starts as soon as possible and runs smoothly. With regards to the Funding Arrangement for supplementary salary support, our office will try to generate the main body (minus milestones) of a draft Funding Arrangement in the next few days. We have not heard from you regarding the milestones in Dr. Tronko's letter dated April 12th. As you may recall, I forwarded the letter and my response to you with a note requesting that you consult with Dr. Tronko on the milestones and other management issues that he referred to in his letter. Were you able to discuss them and finalize the milestones during your meetings with Dr. Tronko? I will most likely visit Kiev in the next month to finalize the Funding Arrangement. If the milestones are not finalized, we will have to write the Funding Arrangement in a more generic way so that it will become effective when the milestones are finalized by you and Dr. Tronko.

2. Schedule of equipment purchases We expect that a recommendation for schedule for the equipment purchases would be made by a Scientific Management Team, working with the individual(s) involved in the purchase and shipment of the equipment. We envision that, with few exceptions, DOE would defer to the recommendations of the individuals directly responsible for implementing the project. Our view is that this kind of decision requires a definition of those individuals making the decision and the process that they will use. However, we are still unclear about the organizational structure and processes that are in place to manage the project. While we would like to consult with you during your development of the structures and processes required to manage the project, we envision that we would play only a minor role, if any, in decisions such as how or whether to stagger the purchase of equipment. We would be happy to schedule a conference call with the interested parties to discuss your recommendations regarding the schedule of equipment and supply purchases for study.

3. Dr. Anspaugh's May 5th fax. Our office called several times to discuss that issue and others regarding the thyroid studies with you, but you were unavailable. When we could not get in touch with you I called Jake Wechselberger at the NRC, but he was unable to resolve the issue. I am sorry that you have been unavailable to talk to our office since you returned from your travels. It is clear that open communication, a defined management structure and clear processes for how decisions are made regarding equipment and supplies and other aspects of project management would go a long way in preventing these misunderstandings. Our office feels that it is essential that we maintain open communication with you, as the NCI Project Manager, and that we all work together to ensure that the projects are more efficiently managed. We hope that your schedule will permit regular interactions with our office so that we can accomplish these goals.

Please call if you would like to discuss any of these issues or if you have any questions.

Sincerely yours,

Elaine K Gallin

Elaine K. Gallin, Ph.D.
Deputy Director
Office of International Health Programs, EH-63

cc: Dr. Lynn Anspaugh, LLNL
Dr. Faye Austin, NCI
Mr. Jacob Wechselberger, NRC
FRETTERS

From: Lynn Anspaugh (5/11/96)
To: Gil Beebe
CC: Andre Bouville
Subject: Time:12:44 PM
OFFICE MEMO Meeting on Monday Date:5/11/96

Dear Gil,

As Sheilah told you before, she and I are planning on arriving at NCI on Monday at 8:30 a.m. Our intent is to come away from this meeting with at least a partial list of equipment that we can work on. It does not have to be complete and all questions do not have to be resolved, but we need at least some final answers from this meeting.

I would also like some time at the beginning of the meeting to discuss my view of the timing and priorities for the project. If you all can agree with (or modify) my proposal, it will be of great help to us in defining priorities.

There are also some general problems that we need to think about. In the past, and lacking any response from NCI, I had canceled the orders for chemicals for the determination of iodine in urine. If someone wants to revisit this question, I think we need to ask the following questions:

1. Does urinary iodine measured today mean anything relative to what urinary iodine might have been ten years ago?

2. Are laboratories in Minsk or elsewhere ready to work with perchloric acid? I hope everyone knows that perchloric acid is extremely hazardous; it should not be used without specially equipped hoods.

3. Why should we repeat work on urinary iodine determinations that has just been done by the WHO? What are the results of that study? [Whoever the proponents are of making such measurements should answer this question in particular.]

Also, we are still hanging on the clinical chemistry aspects of these studies. We continue to have many conversations with Abbott concerning the contract that we have with them. Due to the non-performance of this work, we are in default on this contract, and Abbott is humoring us at the moment out of their sense of good will. We do not expect that this will continue much longer, and that final decisions have to be made.

The contract that we have with Abbott is for 48,327 DM. This was for the delivery of 32 test kits (100 determinations per test kit) each for the measurement of Free T4, HTSH, and Total T4 and for the delivery of associated calibration equipment and controls, etc. This works out to approximately $11 per patient, if all three determinations are made on each patient. If all three measurements were to be made on each patient each year in the two countries, this might be sometime like $700,000 per year. If that is reduced to determinations once every three years, it is about $240,000 per year. I don't think even the latter figure is realistic. Thus, I suggest that whoever favors these measurements develop a pretty powerful, compelling strategy for why they should be done, or that we summarily drop them from consideration. It wouldn't hurt, by the way, to redesign all of these projects completely in view of the realities of life; I just don't think there is money enough to implement the Protocols.

Bruce has opened the door for a return to our amicable relationship, and I have reciprocated with the enclosed message to him. I hope that we can all reach mutual satisfaction with the implementation of the projects.

Lynn

MINUTES
# of the NCI-LLNL staff for evaluation of equipment requests from Dr. Tronko's Institute and approval of procurement
held on 13 May 1966 at NCI

The meeting to determine the equipment/supply needs for the thyroid cancer project in Ukraine was attended by Dr. L. Anspaugh and Ms. S. Hendrickson from LLNL, Dr. E. Mincey and Dr. J. Robbins, advisors, and Drs. Beebe, Bouville and Masnyk, NCI staff.

Dr. Anspaugh opened the discussion by stating that our goal should be to purchase what is needed so that the project can get started. He believed that we need to support the pathology work in Kyiv from the start but questioned the immediate need for the requested vehicles and for selection of the cohort; however if a cohort is required, then we need an established DCC. He then switched to the issue of clinical chemistry and pointed out the high cost of running all the proposed assays. He specifically opposed determination of urinary iodine: WHO has already done a study in Belarus and perchloric acid required for this test is a hazardous material that is going to be very difficult to deliver to eastern Europe.

Dr. Masnyk raised the issue of the misunderstanding generated somehow about a possible cut of the funds available to Ukraine from $500,000 to $300,000. He explained what was behind this misunderstanding, namely that it was just one possible way to phase in the purchases rather than committing all funds up front. But he assured everybody that no cuts were contemplated by NCI.

Ms. Hendrickson explained that it is necessary to establish a data base including all the items required for the project, which then could be phased in; to achieve best pricing on volume purchases, we need the overall requirements. At present there is $625,000 available for Ukraine and $125,000 left for the Belarus equipment/supplies. When the first estimates appear, they are usually higher than the actual purchasing cost.

Discussion next turned to clinical chemistry. Dr. J. Robbins stated that determination of TSH and free T-4 is essential as it is specified in the protocol. It cannot be taken out arbitrarily. We must test for thyroid hormones as we do need to know about hypothyroidism. Dr. Mincey recalled that the Belarus protocol calls for 9 tests done on everyone annually. In Ukraine certain tests are projected for the first year and then only select ones would be considered. Dr. Robbins wondered whether Abbott would provide the IMX unit for just a few assays. Urinary iodine was requested by Belarus but not necessarily by Ukraine. We could test it actually as it is not very costly.

Dr. Mincey listed the proposed tests and the discussion centered on which tests would be the crucial ones and which could be dropped. Running all of them would cripple the budget. Dr. Beebe stated that at this time we can only establish priority of individual tests but we need a larger advisory group to make specific selections. The protocols will have to catch up with funding limitations. All agreed that at present clinical chemistry could be set aside for a while. The top priority should be to set up the cohort for the study.

At this time the group turned its attention to the principal issue of this meeting: equipment requests from Ukraine. It had become obvious to the NCI staff that some of the items requested by the pathology program were also being scheduled to be provided by the EC. Dr. Bouville presented a FAX of the document from Dr. Karaoglou from Bruxelles which listed individual items to which the EC committed itself for delivery in 1996. Most of them appeared also on the request to NCI. To resolve the problem, it was agreed to approve the most recent request list from Dr. Tronko with additional items suggested by Dr. Mitchell for the establishment of DCC, while tabling the requests from Dr. Bogdanova pending the resolution of the EC commitment. At the next trip to Kyiv, this issue will de rediscussed with Dr. Bogdanova.

Dr. Beebe then discussed plans for the next trip to Kyiv. The goal was to address: the operational manual, the process of establishment of the cohort, fixed and mobile team operations and possibly a visit to one of the remote stations to observe actual handling of the required paperwork and examination of some patients.

Ms. Hendrickson reminded everybody that Belarus has still about $225,000 left in the equipment category and Ukraine about $625,000. Dr. Masnyk stated that the mini-busses requested would be used only to transport the examination teams to different sites along with portable equipment. On each site, the teams will be set up in permanent buildings; no examination are planned to be carried out in these busses. This should reduce the cost of such busses considerably. Ms. Hendrickson mentioned two possible models which cost around $30,000 each.

Dr. Anspaugh noted that both the NRC and DOE are under pressure to reduce their budgets. When proposing future funding, they need strong justification and therefore we must exert all effort to start our operations so that we would be able to show what the money is needed for. Dr. Beebe thought that we may be able to have a trial run in September and perhaps we could start screening in October-November time frame.

Ms. Hendrickson stated that she will mail supply and equipment catalogues from three U.S. companies to Belarus and Ukraine which should facilitate the procurement operations considerably. She needs the overall requests to be able to negotiate best prices. Then the individual deliveries could be phased according to program needs. She asked specifically about the two ultrasound units that were listed as required.

After lunch, discussion turned again to the issue of IMX rental, the number of needed tests and their cost. Dr. Mincey calculated that we could easily spend one million dollars per year on these tests alone. The decision was reached to let the IMX contract lapse at present and to return to the issue of individual tests at a later date. Dr. Beebe wondered if it would be possible able to convene the Binational Advisory Committee in July to address this issue. Dr.

Mincey pushed for focusing on only two tests: TSH and anti-TPA, and Dr. Robbins insisted that a baseline should be established in the beginning and then, at a later time, select retesting could be arranged.

The discussion turned to some issues in Belarus. It was agreed that Minsk needs to be fully operational before we should start working on Gomel needs.

Ms. Hendrickson shipped recently a computer for dosimetry and file folders for screening operations. She noted that the Bel-Am project office would be moved to a building near the Vostok Metro station.

Dr. Robbins reported on the tissue banking proposal made by Dr. E. D. Willams, saying that it had gone to the EC for funding. There would be a center at Cambridge plus 4 centers in the CIS with staff. The U.S. was hoped to provide $50-75,000 in funding, but he did not know which agency might support this effort. Dr. Williams' program, if successful, might obviate the need for freezers. It would be useful for biological dosimetry. If the U.S. would provide partial funding, it would be easier for U.S. investigators to have access to the tissue.

Dr. Anspaugh stated that we need to develop a project schedule which would facilitate everybody's work, especially in the area of phasing-in equipment/supplies delivery.

The modified request from Dr. Tronko was approved by the group and signed by Dr. Wachholz. Ms. Hendrickson volunteered to run a comparison of the two lists (the EC and Dr. Bogdanova's) and proceed with initiation of the procurement.

Ihor J. Masnyk
30 Jul 1996

LIST OF EQUIPMENT AND SUPPLY FOR UKRAINIAN THYROID PROJECT

Equipment and Supplies for Data Coordinating Center

Individual components developed from the Recommendations of Dr. H. E. Mitchell (Attached).

Equipment and Supplies for Central Laboratory

Toshiba New Alpha - model TOSBE (SSA-240A)	1
Standard package of system (incl. PVE-375M, 3.75 MHz convex transducer	1
SM-708A 7.5 MHz mechanical sector transducer for small parts (inc. set of waterbag kits)	1
WBK-52M Waterbag kit for SM-708A for the thyroid	10
UIMC-240A Mechanical sector kit for SM 708A	1
UZRI-241A Mounting kit for TP-8700 under keyboard	1
TP-8700 Super sonoprinter incl. 2 cartons paper with 6 rolls	2
PVF-745V "Micro" convex transducer for intraoperative use (vertical type), dual frequency 7.0 MHz (5.0 MHz) radius 45 mm, viewing angle 36 deg.	1
UAGF-021A Biopsy guide for PVF-745V (14-22G)	1
B-310 Thermal paper for TP-8700 (1 carton with 6 rolls, approximately 1200 images)	3
SG-1050 Sonogel, 5 liter container	10
Biopsy/21 Biopsy needles 21G	1000
Biopsy/22 Biopsy needles 22G	1000

ok BMW
5/13/96

OK BWW
5/13/96

LIST OF EQUIPMENT FOR SUPPORTING DOSIMETRY AND RISK ANALYSIS PERSONNEL in year 1 (Group1: Dose reconstruction and Group 2: Information Support)

Computer Hardware:

N	Item	Approximate cost, USD	Q-ty	Approxim. total cost, USD
1	PC with CPU Pentium/133 MHz, RAM 16Mb, 17" SVGA color monitor (2Mb VideoRAM)	2600	2	5200
2	PC with CPU Pentium/133 MHz, RAM 16Mb, 15" SVGA color monitor	2200	2	4400
3	Printer HP DeskJet 5MP	1200	1	1200
4	Cartriges for HP DeskJet 5MP	120	5	600
5	CD-ROM driver (8-speed)	400	1	400
6	Streamer external (TRAVAN TR-3 or TR-1 standard)	400	1	400
7	Cartridges for streamer	30	20	600
8	Voice&Fax Modem 28.8 Kbps	300	2	600
9	Netcard Ethernet NE-2000 (BNC, PCI bus)	100	4	400
10	PC Card ARWID with peripheral	700	1	700

Computer Software:

N	Item	Approximate cost, USD	Q-ty	Approxim. total cost, USD
11	Windows NT (5 license)	1000	1	1000
12	Windows 95	150	3	450
13	RDBMS PC Oracle7 Workgroup Server (5 license)	2400	1	2400
14	Oracle Developer/2000 (for Windows)	5000	1	5000
15	GIS PC ARC/INFO 3.4.x	3600	1	3600
16	ArcView 2.1 for Windows	1300	1	1300
17	MS Office 95 (Professional Kit)	500	1	500
18	MATLAB Compiler (developer version)	1120	1	1120
19	MATLAB C Math Library (developer version)	745	1	745

20	MATLAB Optimization Toolbox	745	1	745
21	MATLAB Signal Processing Toolbox	495	1	495
22	MATLAB System Identification Toolbox	745	1	745
23	MATLAB Control System Toolbox	1120	1	1120

ok BMW
5/13/96

Preliminary Equipment Recommendations for DCC Office

Ukrainian Thyroid Cancer Project

ok BWW
5/13/96

Herman E. Mitchell
May 9, 1996
File: C:\UDCC

Overview:

It is my understanding that the Ukraine DCC should be configured in a manner similar to that of the Minsk DCC. The following recommendations/suggestions are based upon that consideration with several differences. These differences are basically related to issues that I believe are not yet clearly resolved. For example, Minks was configured in their DCC to permit direct connection high-speed transmission lines to the Dispensary and (eventually) to Aksakovchina. The hardware and software for the DCC was purchased, but the actual line was delayed until closer to project startup and resolution of monthly rental costs ($90 per month, as I recall).

A quick review of current Compaq models seemed to indicate that every model type has changed since the Minsk DCC was configured. For example, all Compaq portables are now Pentium based (rather than 486 microprocessors) and they come with a minimum 28.8k modem. All these are good changes of course, but will require that Sheilah and I update models for comparable devices. We will then have to ensure that these models are being distributed in the Ukraine. We had to make a number of modifications based upon country availability for the Minsk DCC.

Basic Computer Configurations for the Ukraine DCC

Desktop Systems:

1). Network Server

The current model which would be comparable to the Minsk DCC is a Compaq Pentium Pro 150mHz server system, with 4 GB disk storage, 32 MB RAM, CD-ROM, 16GB DAT Tape, and ethernet adapter, 15" SVGA monitor.

ok BHW
5/13/96

2). Stat/Epidemiology/Systems Analyst Workstations

3-Systems to be shared by the Epidemiology/Statistics/System Analyst group [I assume there will be at least one statistician, one systems analyst and one epidemiologist in the DCC).

These system should be 133 mHz Pentium, with 16MB RAM, 1.6 GB Hard Disks, ethernet connections, 15" SVGA monitors on two systems, one with 17" monitor, CD-ROM.

3) Data Entry/Programmer Workstations

2-Systems to be shared by data entry and junior programmers. These should be 120 mHz Pentium with 16Mb RAM, 1.0 GB Hard Disk, 15" SVGA Monitors.

4). Portable Systems

Presumably portable systems would be needed for the mobile data collection vans. I would recommend purchasing these as close to the time of study startup as possible. This will permit the best price and latest technology. There is no software development which would require that a portable system be used rather than a desktop.

5). Printers

The Minsk DCC had one Hewlett-Packard LaserJet printer at its main office and one at the Dispensary. The Ukraine DCC will need at least one HP Laserjet at the DCC. HP LaserJet 5MX is the current model, I believe. I would recommend replacing the Dot matrix printers with ink-jet, unless multiple part forms will be required - in which case, dot matrix would be needed. HP DeskJet 850C is a good choice.

6) Modems

I would order 3 modems. Speed depends somewhat on the capability of the telephone system. We limited the Minsk modems to 14.4 baud since it was felt that the telephone system could not handle anything higher. 28.8k baud in more common in this country. We bought ZyXel modems in Minks based upon BelPak's recommendation, this should be checked with the Ukraine telephone company (it is likely to be the same).

ok BMW
5/13/96

7) Software

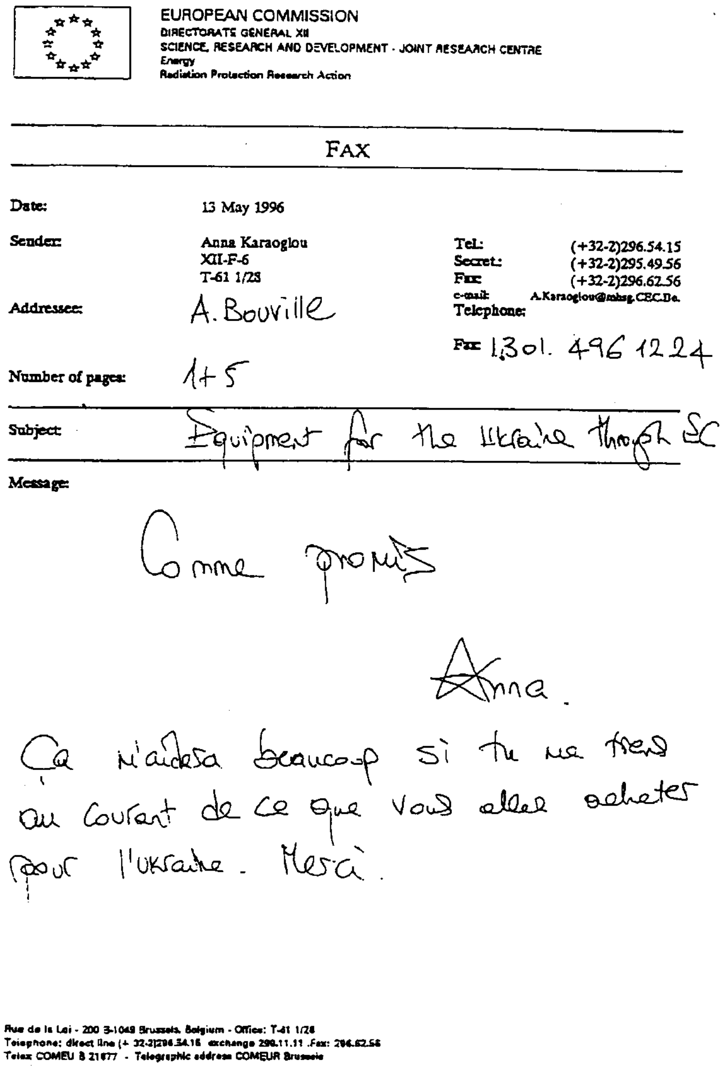
Arthur chose to use Btrieve for his database software and Novell for his network platform. The Ukraine dosimetry group has requested Oracle and Windows NT for the database and network, respectively. I like their choice better than Novell and Btrieve. This decision depends upon the capabilities and experience of the DCC support personnel. If they have Oracle and Windows NT support and can get additional support from the dosimetry group, I would go with Oracle and Windows NT.

8) Supplies, Miscellaneous

Supplies are basically the same, but will depend upon printer choice. We need to know how they will wire their network before BNC connectors are ordered. Will it be thin ethernet or twisted pair (10-based T)?

9) Communications

If the high-speed line is not being implemented, we do not need transceiver, Newport boards, or Citrix system.



EUROPEAN COMMISSION
DIRECTORATE GENERAL XII
SCIENCE, RESEARCH AND DEVELOPMENT - JOINT RESEARCH CENTRE
Energy
Radiation Protection Research Action

FAX

Date: 13 May 1996

Sender: Anna Karaoglou
XII-F-6
T-61 1/25

Tel.: (+32-2)296.54.15
Secret.: (+32-2)295.49.56
Fax: (+32-2)296.62.56
e-mail: A.Karaoglou@mhsg.CEC.Be.

Addressee: A. Bouville

Telephone:

Fax 1.301. 496 1224

Number of pages: 1+5

Subject: Equipment for the Ukraine through SC

Message:

Comme promis

Anna.

Ça m'aidera beaucoup si tu me tiens au courant de ce que vous allez acheter pour l'Ukraine. Merci.

Rue de la Loi - 200 B-1049 Brussels, Belgium - Office: T-61 1/28
Telephone: direct line (+ 32-2)296.54.15 exchange 299.11.11 .Fax: 296.62.56
Telex COMEU B 21877 - Telegraphic address COMEUR Brussels

FOR THE UKRAINE => Goods are to be delivered to the Institute of Endocrinology and Metabolism, Kiev.

ANNEX

Action 1996

EQUIPMENT FOR OPERATION THEATRE AND HISTOPATHOLOGY

1. Operating Theater Table, 4 section general purpose, with fully mobile hydraulic base, movements to include, trendelenburg tilt, reverse trendelemburg, lateral tilt, chair supplied with x-ray cassette spade (Mechanical, 2 pcs.).

2. Autoclave bench (2 pcs).

3. Lights - Ceiling Mounted Operating Light, with heat protection filters, 10 x 50 watt low voltage halogen bulbs, spare bulb, focus control, sterilisable handle, self arresting height adjustable (2 pcs.).

4. Mobile Operating Light, with 3 light sources, similar specification as above (2pcs.). (If possible with autonomic electric supply - batteries).

5. Magnifying forehaed optics for lighting for surgeon (2 pcs.).

6. Large Radical Set of Surgical instruments for neck operations (50 denominations, 113 items) and Small Radical Set of Surgical instruments for neck operations (36 denominations, 85 items)

7. Electrosurgical System (Diathermy) mounted on mobile trolley, with foot switch, power range 50-100 watts, selection of diathermy pencils (4 pcs.).

8. Surgical Suction Pump, 2 collecting jars, 2 liter capacity, mounted on mobil stand. Vacuum maximum in excess of 600 mm Hg (8 pcs.).

9. Stretcher Trolley - complete with impact absorbing buffer to minimize damage to doors and walls, four antistatic wheels, with wheel brakes, antistaic mattress, side rails, drip pole, drip pole socket, blanket tray, trolley to be able to in head down position (2 pcs.).

10. Simple trolley for patients transportation. (6 pcs.).

11. Photocamera with objectives for intraoperative shooting (1 pcs.).

12. Paraformaline chamber for instrument sterilization (2 pcs.).

13. Medical Coats for Operation Staff and Staff (600 pcs., preferably green).

14. Coton-paper sheets (1.000 pcs., preferably green).

15. Metal boxes for sterile materials of different sizes (50 pcs.).

16. Laryngoscopes (5 pcs.).

17. Apparatus for narcosis & respiration (2pcs.).

18. Monitors for anestethic machine, paramteers include ECG/Respiration, non invasive blood pressure, pulse oximetry, temperature and recorder module with all accessories (1 pcs.).

19. Machine (tonometer) for measurement arterial pressure (indirect method. 10 pcs.).

20. Tracheo-laryngeal masks (15 pcs.).

21. Fibrooptical bronchoscope (1 pcs.).

22. Vasocan Brauniie diametr 1,7 mm / 16GOD (1.000 pcs.).

23. Viggo Venflon 2 diametr 16 G/1,7 mm O.D. (1.000 pcs.).

24. Viggo Venflon 2 diametr 17 G/1,4 mm O.D. (1.000 pcs.).

25. Miniset Vein Infusion Set 19 G x 1,9 cm (1/4') (1.000 pcs.).

26 Butterfly-19 1,1 mm diametr 0,8 mm. (1.000 pcs.).

HISTOPATHOLOGY

27. Double headed microscope for histopathological diagnosis and teaching, with achromatic objective lenses, times 63, 25, 10 4 and 2 or a similar range of magnification.

28. Rotary microtome with knives and disposable microtome blades (50 blades).

29. Vacuum unit for Shandon Histokinette processor.

30. Analytical balance (e.g. Sartorius AC 1205)

31. 7 adjustable pipettes (2 of 2 µl, 1 of 200 µl, 2 of 1.000 µl and 2 of 5.000 µl) with tips (e.g. Pipetman pipetes from Anachem, code numbers P2, P200, P1000 and P5000; tips to be in bags of 100 for the 2 µl pipette and 1000 for the remainder).

32. 10 metal slide racks (each holding 25 microscope slides for staining).

33. Glass troughs (capacity 400 mls, large enough to hold one slide rack (item 6) each).

34. 12 measuring cylinders (4x25 mls, 4x100 mls, 4x500 mls).

35. 5 timers, battery operated, small clip on type.

36. Plastic universal containers. 1 box of 400

37. 5 racks to hold bijous.

38. Bijous (1 box of 700).

39. Haematoxylin (Gill no 3) 12 kg.

40. Eosin B, 100 g.

41. Alcian blue 100 g.

42. Congo red 100 g.

43. Giemsa stain 100 g.

44. Methylene blue 100 g.

45. Silver nitrate 100 g.

46. Xylene AR grade 200 L.

47. Methanol AR grade 200 L.

48. Ethanol AR 8x2,5 L.

49. Paraffin for tissue embedding (25 kg.)

50. Hydogen peroxidase GPR 30% w/v 1L.

51 Strept ABC kit.

52. Antibodies: swine anti-rabbit HRP, rabbit anti-human thyroglobulin, rabbit anti-human calcitonin.

53. Plastic cassettes for holding histological specimens (No. 5.000).

54. Cassette lids (metal) (No. 500).

55. Disposable microtome blades (No. 50 boxes of 50).

56. Cryospray (No. 30 bottles).

57. OCT for embedding frozen material (No. 10 bottles).

58. Coverslips (22x50 mm) (No. 50 boxes of 100).

59. Microscope slides (Goldstar) (No. 5.000).

60. Depex (histological mountant) (No. 5x500 mls).

61. Formaldehyde (buffered concentrate) (No 20x5 litres).

62. Nikon focusing magnifier ref. MPC 9300. (N. 1)

63. Automatic System for Slide Demonstration (No. 1).

64. Automatic System for Demonstration of Tables, Pictures, etc., on transparent films (overhead projector) (No. 1).

65. Transparent Films for overhead projector (cases) (No. 20).

66. Histoaumatic slide Stainers (for small amount of slides) (No.1).

67. PH/ISE Meter (No.1).

68. Microslides Storage Systems (No.1).

69. Tissue Blocks Storage Systems (No.1).

70. Epon Accelerator DMP 30 (250 ml) (No.2).

71. Epon Hardener DDSA (11) (No. 2).

72. Epon 812 (11) (No. 2).

73. Epon Hardener MNA (11) (No. 2).

74. Grids for Transmission Electron Microscopy
Spi-Grid collection I (Cu) G75 (cases) (No. 30)
G100 (cases) (No.20).

75. Glass Strips (25x6 . 35x400 mm)
for Transmission Electron Microscopy (cases) (No. 10).

76. Osmium Tetroxide (1g) (15g. Sigma).

77. Lead citrate Trihydrate (25g) (75g. Sigma).

78. Uranyl Acetate Dihydrate (100 g Sigma)

79. Capsules plastic or gelatine d5-7 mm (10.000 Sigma).

80. EM Sheets Mesh Fine Grids type F100 (100 pcs/pack) (30 4180 01347).

81. EM Sheets Mesh Fine Grids type F150 (100 pcs/pack) (90 4180 01355).

82. EM Sheets Mesh Fine Grids type F200 (100 pcs/pack) (50 4180 01363).

83. Glutaraldehyde Grade 25% for EM (100 ml) (11 Sigma).

84. Ultramicrotome MT-7[1]	(1)
85. Glass Knife Maker for Ultramicrotome[1]	(1).
86. Ultrastainer for Electron Microscopy[1]	(1)
87. Mercury Battery H-22D/B 29 . 7V[1]	(2 3020 00178).
88. Mercury Battery H-12D/B 16 . 2V[1]	(14 3020 00313).
89. Mercury Barrery H-6D/B 8 . 1V[1]	(2 3020 00381).
90. Thin Foil Aperture for O.L. (20-40-60-120)[1]	(7 4180 00433).
91. Thin Foil Aperture for C.L. (20-200-300-400)[1]	(5 4180 00565).
92. Fixed Aperture for C.L.-P.P. (500 C.L-1)[1]	(5 6000 65316).
93. Fixed Aperture for C.L.-P.P. (1000 C.L-2)[1]	(5 4180 01251).
94. Tantalum Boat for Clening (for Tnin Foil aperture)[1]	(5 6000 02691).
95. Tantalum Boat for Clening (for Disk Type aperture)[1]	(5 6000 02969).

+ Chest freezer −70°C .

Dose Reconstruction Program
(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

May 16, 1996

TO: Anna Karaoglou—011-32-2-296-6256
cc: André Bouville—1-301-496-1224

FROM: Sheilah Hendrickson Sheilah TELE NO: (510) 424-6410

SUBJECT: Equipment List for Ukraine Thyroid Cancer Study

Hello Anna,

Thank you for sending us the list of equipment for the Operation Theatre and Histopathology that will be furnished by the EC.

I am sending you the original list of equipment and supplies requested by the Ukraine for the Central Laboratory and Pathology Laboratory Support. As André probably told you, I have not yet compared the EC list (equipment being furnished) with the Ukraine lists for the Central Lab and Pathology Lab. I also believe that during the visit of the US delegation in Kiev next week they will discuss duplication of items (equipment being furnished by EC and currently being requested from the US) to determine the feasibility of using EC furnished equipment for the US project as well or if it will be located elsewhere.

In any case, once the U.S. approved lists for the Central and Pathology Laboratories are finalized (which will most likely be in phases), I will be happy to send you copies.

Please let me know or André, if you have any questions.

My best regards to you and say hello to Jaak for me.

We are transmitting 5 pages (including this cover sheet).

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-453, Livermore, CA 94551-9900
University of California Fax (510) 424-6408 Telex (910) 386-8339

Dose Reconstruction Program

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anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

June 5, 199

TO: André Bouville
Ihor Maznyak

TELE NO: 301-436-9326 FAX NO: 301-496-1224

FROM: Sheilah Hendrickson Sheilah TELE NO: (510) 424-6410

SUBJECT: Ukraine Thyroid Project

MESSAGE:

André:
Per your e-mail, I am sending you my May 29th fax. I hope you can read this copy. I hope this is what you were asking for. I will send the Excel spreadsheet via e-mail. This will be an Excel 4.0 file for the Macintosh. Let me know if I need to save or convert it another way so your machine can read it. Thank you and Gil Beebe for sending me the trip reports from Randy, Jack and Gil. These were very helpful.

Ihor:
In both Randy Brill's trip report and e-mail he mentions that Dr. Bogdanova gave you a list or form of the urgent needs for consumables (other things?) she checked off. Could you send me this list? I would appreciate a copy of your trip report as well when it is complete.

Thanks!

We are transmitting 9 pages (including this cover sheet).

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-286 Livermore, CA 94551-9900
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Dose Reconstruction Program

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hendrickson3@llnl.gov

May 29, 1996

TO:		Telephone	Fax
	Lynn Anspaugh	510-424-6409	510-424-6408
	Gil Beebe	301-436-5067	301-496-1854
	Mohandas Bhat	301-903-1719	301-903-1413
	André Bouville	301-436-9326	301-4~~3~~96-1224
	Randy Brill	508-856-4236	508-856-4572
	Elaine Gallin	301-9032105	Same as Bhat
	Ihor Maznyak	Same as Bouville	Same as Bouville
	Everett Mincey	604-888-7417	604-888-0471
	Jack Robbins	301-436-5761	301-402-0387

FROM: Sheilah Hendrickson TELE NO: (510) 424-6410

SUBJECT: Ukraine Thyroid Project

MESSAGE:

The results of comparing the list of equipment that is being provided by the EC and the list (complete) from Ukraine follows. Per agreement, I will also send this to Anna Karaoglou once we clarify the questionable items.

Please note:

(1) This is our first draft of the spreadsheet/database for Ukraine.
(2) This is our best estimate of "exact word-for-word matches" or what we think are "near-matches"
(3) Questionable matches—André please advise me to whom I should address these items.
(4) I will refer to the list from the European Commission as the "EC Nbr."
(5) I will refer to the list from Ukraine as "LLNL Nbr."

We are transmitting 13 pages (including this cover sheet).

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program
Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-286 Livermore, CA 94551-9900
University of California Fax (510) 424-6408 Telex (910) 386-8339

EC Nbr	LLNL Nbr	Comments
27	97	Similar. Does not include photography equipment. EC is providing a double headed and the Ukraine request was for either a 2 or 4 head.
30	110	Both balances, but are they the same?
31	126–132	Different sizes?
32–33	98	Is this the microscope slide storage system?
36	101	Are these vacutainers?
39	146	MATCH
40	147	MATCH
41	149	MATCH
42	150	MATCH
43	148	MATCH
44	157	MATCH
45	158	MATCH
46	162	MATCH—Do we use the same grade of AR grade 200 L?
47	164	MATCH—Do we use the same grade of AR grade 200 L?
48	163	MATCH—Do we use the same grade of AR grade 200 L?
49	144	MATCH
50	168	MATCH
52	169–175	Some similarities, but different
53	134	Different description
55	135	MATCH
56	135	MATCH
57	142	Different description
58	138	Cover glasses?
59	137	MATCH
61	155	Same as paraformaldehyde?
63	114	Slide projector?
66	109	MATCH
67	111	MATCH
68	112	MATCH
69	113	MATCH
70	178	MATCH
71	179	MATCH

72	180	MATCH
73	181	MATCH
74	182–184	MATCH
75	185	MATCH
76	156	MATCH
77	160	MATCH
78	161	MATCH
79	140	MATCH
83	154	MATCH
CHEST FREEZERS -70oC	100	This is a chest freezer. The others are portable.

André and Randy—For the items that are "matches" and what is determined to be "matches" I will keep on the spreadsheet/database. However, please advise me if ALL or SELECTED match items should be excluded from being purchased. If I remember correctly, the U.S. team that just returned from Kiev was also going to determine if any items that the EC was providing needed to be purchased from the U.S. as well.

Randy and André—Could you update me about the above mentioned trip as it relates to equipment discussions?

Ihor—I also understand from Dr. Tereshchenko that he has solved the issue of tax exemptions, etc., for equipment to be shipped by us to Ukraine. Dr. Tereshchenko stated that he has documents to this effect and that these documents were provided to you for transmission to me. Please be sure that these documents are promptly sent to me.

Also, — IMX in Belarus:
Per our May 13th meeting, and discussion with LLNL Procurement and Abbott (both the represenative for Europe and their contract procurement department)—We are processing the cancellation of the IMX order. Abbott advised they will pick up the IMX as there is need in other hospitals/laboratories and requesed I notify Minsk. Abbott understands our situation and looks at this as "strictly business." They hope they can work and help us in the future both in Belarus and Ukraine.

If anyone has any questions or comments, please contact me by telephone, e-mail, or fax.

Sheilah Hendrickson
Project Manager
Equipment and Supplies

FOR THE UKRAINE => Goods are to be delivered to the Institute of Endocrinology and Metabolism, Kiev.

ANNEX

Action 1996

EQUIPMENT FOR OPERATION THEATRE
AND HISTOPATHOLOGY

1. Operating Theater Table, 4 section general purpose, with fully mobile hydraulic base, movements to include, trendelenburg tilt, reverse trendelemburg, lateral tilt, chair supplied with x-ray cassette spade (Mechanical, 2 pcs.).

2. Autoclave bench (2 pcs).

3. Lights - Ceiling Mounted Operating Light, with heat protection filters, 10 x 50 watt low voltage halogen bulbs, spare bulb, focus control, sterilisable handle, self arresting height adjustable (2 pcs.).

4. Mobile Operating Light, with 3 light sources, similar specification as above (2pcs.). (If possible with autonomic electric supply - batteries).

5. Magnifying forehaed optics for lighting for surgeon (2 pcs.).

6. Large Radical Set of Surgical instruments for neck operations (50 denominations, 113 items) and Small Radical Set of Surgical instruments for neck operations (36 denominations, 85 items)

7. Electrosurgical System (Diathermy) mounted on mobile trolley, with foot switch, power range 50-100 watts, selection of diathermy pencils (4 pcs.).

8. Surgical Suction Pump, 2 collecting jars, 2 liter capacity, mounted on mobil stand. Vacuum maximum in excess of 600 mm Hg (8 pcs.).

9. Stretcher Trolley - complete with impact absorbing buffer to minimize damage to doors and walls, four antistatic wheels, with wheel brakes, antistaic mattress, side rails, drip pole, drip pole socket, blanket tray, trolley to be able to in head down position (2 pcs.).

10. Simple trolley for patients transportation. (6 pcs.).

11. Photocamera with objectives for intraoperative shooting (1 pcs.).

12. Paraformaline chamber for instrument sterilization (2 pcs.).

13. Medical Coats for Operation Staff and Staff (600 pcs., preferably green).

14. Coton-paper sheets (1.000 pcs., preferably green).

15. Metal boxes for sterile materials of different sizes (50 pcs.).

16. Laryngoscopes (5 pcs.).

17. Apparatus for narcosis & respiration (2pcs.).

18. Monitors for anestethic machine, paramteers include ECG/Respiration, non invasive blood pressure, pulse oximetry, temperature and recorder module with all accessories (1 pcs.).

19. Machine (tonometer) for measurement arterial pressure (indirect method. 10 pcs.).

20. Tracheo-laryngeal masks (15 pcs.).

21. Fibrooptical bronchoscope (1 pcs.).

22. Vasocan Braunüe diametr 1,7 mm / 16GOD (1.000 pcs.).

23. Viggo Venflon 2 diametr 16 G/1,7 mm O.D. (1.000 pcs.).

24. Viggo Venflon 2 diametr 17 G/1,4 mm O.D. (1.000 pcs.).

25. Miniset Vein Infusion Set 19 G x 1,9 cm (1/4") (1.000 pcs.).

26 Butterfly-19 1,1 mm diametr 0,8 mm. (1.000 pcs.).

HISTOPATHOLOGY

97 → 27. Double headed microscope for histopathological diagnosis and teaching, with achromatic objective lenses, times 63, 25, 10 4 and 2 or a similar range of magnification. — This is similar but different. Does not include photograp equipment

28. Rotary microtome with knives and disposable microtome blades (50 blades).

29. Vacuum unit for Shandon Histokinette processor.

110 30. Analytical balance (e.g. Sartorius AC 1205) Both balances, but description is differen

126-132 31. 7 adjustable pipettes (2 of 2 µl, 1 of 200 µl, 2 of 1.000 µl and 2 of 5.000 µl) with tips (e.g. Pipetman pipetes from Anachem, code numbers P2, P200, P1000 and P5000; tips to be in bags of 100 for the 2 µl pipette and 1000 for the remainder). Different sizes?

98 32. 10 metal slide racks (each holding 25 microscope slides for staining). Is this the microscop slide storage system?

33. Glass troughs (capacity 400 mls, large enough to hold one slide rack (item 6) each).

34. 12 measuring cylinders (4x25 mls, 4x100 mls, 4x500 mls).

35. 5 timers, battery operated, small clip on type.

101 36. Plastic universal containers, 1 box of 400 Are these vacutainers?

37. 5 racks to hold bijous.

38. Bijous (1 box of 700).

146 39. Haematoxylin (Gill no 3) 12 kg.

147 X 40. Eosin B, 100 g.

149 X 41. Alcian blue 100 g.

150 X 42. Congo red 100 g.

148 X 43. Giemsa stain 100 g.

157 X 44. Methylene blue 100 g.

158 X 45. Silver nitrate 100 g.

162 X 46. Xylene AR grade 200 L.

164 X 47. Methanol AR grade 200 L.

163 48. Ethanol AR 8x2,5 L.

144 X 49. Paraffin for tissue embedding (25 kg.)

168 X 50. Hydogen peroxidase GPR 30% w/v 1L.

51 Strept ABC kit.

169-175 52. Antibodies: swine anti-rabbit HRP, rabbit anti-human thyroglobulin, rabbit anti-human calcitonin.
Some similarities, but different

134 53. Plastic cassettes for holding histological specimens (No. 5.000). Different description

54. Cassette lids (metal) (No. 500).

135 55. Disposable microtome blades (No. 50 boxes of 50).

143 56. Cryospray (No. 30 bottles).

142 57. OCT for embedding frozen material (No. 10 bottles). – different description

138 58. Coverslips (22x50 mm) (No. 50 boxes of 100). – cover glasses

137 59. Microscope slides (Goldstar) (No. 5.000).

60. Depex (histological mountant) (No. 5x500 mls).

155 61. Formaldehyde (buffered concentrate) (No 20x5 litres). ≃ paraformaldehyde

62. Nikon focusing magnifier ref. MPC 9300. (N. 1)

114 — 63. Automatic System for Slide Demonstration (No. 1). Slide projector?

64. Automatic System for Demonstration of Tables, Pictures, etc., on transparent films (overhead projector) (No. 1).

65. Transparent Films for overhead projector (cases) (No. 20).

109 66. Histoaumatic slide Stainers (for small amount of slides) (No.1).

111 67. PH/ISE Meter (No.1).

112 68. Microslides Storage Systems (No.1).

113 - 69. Tissue Blocks Storage Systems (No.1).

178 70. Epon Accelerator DMP 30 (250 ml) (No.2).

179 71. Epon Hardener DDSA (1l) (No. 2).

180 72. Epon 812 (1l) (No. 2).

181 73. Epon Hardener MNA (1l) (No. 2).

182-184 74. Grids for Transmission Electron Microscopy
Spi-Grid collection I (Cu) G75 (cases) (No. 30)
G100 (cases) (No.20).

185 75. Glass Strips (25x6 . 35x400 mm)
for Transmission Electron Microscopy (cases) (No. 10).

156 76. Osmium Tetroxide (1g) (15g. Sigma).

160 77. Lead citrate Trihydrate (25g) (75g. Sigma).

161 78. Uranyl Acetate Dihydrate (100 g Sigma)

140 79. Capsules plastic or gelatine d5-7 mm (10.000 Sigma).

80. EM Sheets Mesh Fine Grids type F100 (100 pcs/pack) (30 4180 01847).

81. EM Sheets Mesh Fine Grids type F150 (100 pcs/pack) (90 4180 01855).

82. EM Sheets Mesh Fine Grids type F200 (100 pcs/pack) (50 4180 01863).

154 83. Glutaraldehyde Grade 25% for EM (100 ml) (11 Sigma).

84. Ultramicrotome MT-7[1]	(1)
85. Glass Knife Maker for Ultramicrotome[1]	(1).
86. Ultrastainer for Electron Microscopy[1]	(1)
87. Mercury Battery H-22D/B 29 . 7V[1]	(2 3020 00178).
88. Mercury Battery H-12D/B 16 . 2V[1]	(14 3020 00313).
89. Mercury Barrery H-6D/B 8 . 1V[1]	(2 3020 00381).
90. Thin Foil Aperture for O.L. (20-40-60-120)[1]	(7 4180 00433).
91. Thin Foil Aperture for C.L. (20-200-300-400)[1]	(5 4180 00565).
92. Fixed Aperture for C.L.-P.P. (500 C.L-1)[1]	(5 6000 65316).
93. Fixed Aperture for C.L.-P.P. (1000 C.L-2)[1]	(5 4180 01251).
94. Tantalum Boat for Clening (for Tnin Foil aperture)[1]	(5 6000 02691).
95. Tantalum Boat for Clening (for Disk Type aperture)[1]	(5 6000 02969).

100 + Chest freezer –70°C . This is a chest freezer. The others are portable

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

✓

TELEFAX MESSAGE

TO:

Telefax: (510) 424-6408
Name & Address: Ms. Sheilah Hendrickson
Lawrence Livermore National Laboratory
University of California
P.O. Box 808, L-453
Livermore, CA 94551-9900

FROM:

Telephone: (301) 496-9326 Telefax: (301) 496-1224
Name & Address: Dr. Ihor Masnyk
Radiation Effects Branch
National Cancer Institute
Executive Plaza North, Room 530
Bethesda, MD 20892

DATE: June 6, 1996

NUMBER OF PAGES INCLUDING COVER PAGE: 3

Memo : to Dr. Bruce W. Wachholz
From: I. J. Masnyk
Subject: Equipment/supplies Request for Pathology Laboratory
Ukr-Am Thyroid Cancer Project
Date: 6 Jun 96

An informal session was held with Dr. Bogdanova, Dr. Robbins, Dr. Brill and me on the 24 May, the last day of our visit to Dr. Tronko's Institute of Endocrinology and Metabolism (ref: trip report) to discuss her request for equipment and supplies. Evaluating the overall request submitted by Dr. Tronko, we realized that the European Community assigned funds for procuring equipment and supplies for Dr. Bogdanova which paralleled her request to us. Therefore, taking advantage of our presence in Kyiv, we explained to Dr. Bogdanova that, since she is about to receive most if not all items from EC, we could not approve them under our project. Her position was that she actually received very little thus far and immediately deleted those items from her list presented to us. She was worried that the project will start without her having the necessary tools to do her job. After prolonged exchange between her and the American group, it was agreed that we will wait for the deliveries from EC, and if there should be shortages, we will address them at a later stage to make sure that all that is required will be available.

In the meantime Dr. Bogdanova told us she has critical need for a number of reagents. A list was provided and we agreed to submit it to LLNL for processing. The list is appended. No other items on the list were approved for procurement at this time.

Finally, Dr. Bodgdanova addressed the problem of tasks projected for the first quarter. She already has data in her laboratory on thyroid cancers going back to 1987. She feels that she should be allowed to extract the cases from that period which would be then available for our study. Even though, it was pointed out to her that this was not in the protocol and that the cohort has not yet been established, it could be added to the protocol and we agreed to add a subtask 7.3 to the list provided and agreed to by Dr. Tronko, with 3 man-months of effort allocated to it.

Text to be added to the list of tasks:

"7.3 Assemble a bank of morpbologic material from the rayons representing the cohort selection so that they would be available for review when the cohort is selected."

cc:
Anspaugh
Beebe
Bouville
Brill
Gallin
Hendrickson
Robbins

List of critically needed reagents for the Pathology Laboratory

Concur
BWW
6/6/96

Hematoxylin (Gill No. 3)	12 kg
Eosin B	100 g
Xylene AR grade	200 L
Methanol AR grade	200 L
Ethanol AR grade	8x2.5 L
Paraffin for tissue embedding	25 kg
Hydrogen peroxide GPR 30% w/v	1 L
Plastic cassettes for holding histological specimens	5,000
Disposable microtome blades	50 boxes of 50
Cryospray	30 bottles
Cover slips (22x50 mm)	50 boxes of 100
Microscope slides (Goldstar)	5,000
Depex (histological mountant)	5x500 ml
Formaldehyde (buffered concentrate)	20x 5 L
Epon Accelerator DMP 30 (250 ml)	2
Epon Hardener DDSA (1l)	2
Epon 812 (1l)	2
Epon Hardener MNA (1l)	2
Grids for Transmission Electron Microscopy	
Spi-Grid collection I(Cu)	30 cases G75
	100 cases G100
Osmium tetroxide	1 g (15 g Sigma)
Uranyl Acetate Dihydrate	100 g (Sigma)
Capsules plastic or gelatine d5-7 mm	10,000 (Sigma)
Glutaraldehyde Grade 25% for EM	100 ml (1l Sigma)

Dose Reconstruction Program

(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

June 18, 1996

TO: Anna Karaoglou—011-32-2-296-6256
André Bouville—1-301-496-1224
Randy Brill—1-508-856-4572

FROM: Sheilah Hendrickson Sheilah **TELE NO:** (510) 424-6410

SUBJECT: Equipment List for Ukraine Thyroid Cancer Study

MESSAGE:

Dear Anna,

I apologize for the delay in providing you a comparison of the lists for equipment and supplies for Ukraine. There are 30 "matches" and 11 items with similar descriptions that will need to be clarified during my July 1 trip to Kiev (We were able to clarify some items with Dr. Randy Brill from the American team.). Following are the results. I have used your numbering system (EC Nbr below) from the list you provided to André against the original list from the Ukraine. We will be duplicating some items as indicated below.

Also, in discussion with André, do you think it would be a good idea for me to meet and establish communications with your office in Kiev? How do you see LLNL (for the U.S.) updating you (EC)? Should we share requests for equipment and supplies or a list of items we purchase and deliver? Also, I would think it would be most helpful for both the US and EC to know when items are expected or actually delivered. I would appreciate your comments and suggests as well as if it is best to communicate with your EC office in Kiev.

We are transmitting 3 pages (including this cover sheet).

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program
Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-286 Livermore, CA 94551-9900
University of California
Fax (510) 424-6408
Telex (910) 386-8339

EC Nbr	Item (not full description)	Remarks
27	Microscope	We will purchase either a 2 or 4 head or just photography attachment depending if Pathology or Cytology receives you microscope.
30	Balances	Clarify
31	Copier	Clarify size specifications
32–33	Metal slide racks/glass troughs	Clarify
36	Plastic universal containers	Same as vacutainers?
39	Haematoxylin	Match—U.S. will order
40	Eosin	Match—U.S. will order
41	Alcian blue	Match
42	Congo red	Match
43	Giemsa stain	Match
44	Methylene blue	Match
45	Silver nitrate	Match
46	Xylene	Match—U.S. will order
47	Methanol	Match—U.S. will order
48	Ethanol	Match—U.S. will order
49	Paraffin	Match—U.S. will order
50	Hydrogen peroxidase	Match—U.S. will order
52	Antibodies	Similarities—Clarify
53	Plastic cassettes	Clarify
55	Disposable microtome blades	Match—U.S. will order
56	Cryospray	Match—U.S. will order
57	OCT for embedding	Match—U.S. will order
58	Coverslips	Clarify
59	Microscope slides	Match—U.S. will order
61	Formaldehyde	Same as paraformaldehyde?—Clarify
63	Slide project	Clarify
66	Histoaumatic slide stainers	Match
67	PH/ISE Meter	Match
68	Microslides Storage Systems	Match
69	Tissue Blocks Storage Systems	Match
70	Epon accelerator	Match—U.S. will order

EC Nbr	Item (not full description)	Remarks
71	Epon Hardener DDSA	Match—U.S. will order
72	Epon 812	Match—U.S. will order
73	Epon Hardener MNA	Match—U.S. will order
74	Grids	Match—U.S. will order
75	Glass Strips	Match
76	Osmium Tetroxide	Match—U.S. will order
77	Lead citrate Trihydrate	Match
78	Uranyl Acetate Dihydrate	Match—U.S. will order
79	Capsules plastic or gelatine	Match—U.S. will order
83	Glutaraldehyde Grade	Match—U.S. will order
Chest Freezers -70 degree C		Portables requested from the U.S.

Anna, if you prefer, you can send me a reply by e-mail. My e-mail address is

hendrickson3@LLNL.gov

I will be leaving for Minsk on Friday, June 21. André will be on the same trip to both Minsk and Kiev. We will also try to contact you during this time.

My best regards and hello to Jaak!

Author: Elaine Gallin at EH-07
te: 7/10/96 5:54 PM
iority: Normal
O: CHERIE GIANINO
TO: MOHANDAS BHAT
TO: RUTH NETA
TO: JOSEPH WEISS
Subject: Re: Just a small note
---------------------------- Message Contents -----------------------------

Forward Header

Subject: Re: Just a small note
Author: Sheilah.Hendrickson@quickmail.llnl.gov_at_INTERNET at X400PO
Date: 7/10/96 2:09 PM

RE>Just a small note 7/10/96

Dear Everett:
Thank you for your message. I hope your Russian studies are going well.

Re Kiev. Unfortunately unless we asked specific questions about Minsk or
Kiev, NCI does not give us much information, present or future. It has
en suggested that I read the operations manual, but I do not think this
ould supersede project management and integration of all participants.
ynn and I
are waiting for the "promised" timeline schedule which NCI said they would
provide at our May 13th meeting.

It is my plan to ask Ihor when they plan to have you involved for both
Belarus
and Ukraine so I can plan for the equipment and supplies. I will be
receiving
equipment lists from Minsk and Kiev approx July 15 for equipment and
supplies
for the next 12 months. I will be sharing this info with everyone.

Please keep in mine that LLNL needs time to research, purcahse and ship. So
the sooner we have info we can deliver things when needed.

We'll keep in touch. Again thanks for your e-mail.
Sheilah

Date: 7/9/96 10:52 PM
To: Sheilah Hendrickson
From: Everett K. Mincey
Dear Sheilah:

st a small note to let you know that I am in St. Petersburg for July,
udying
Russian. I am able to access my Compuserve email box directly from here
using
the telephone system and my laptop. If you have questions about materials

and
supplies which concern me, please send email and I will respond since I
check
the mailbox daily. There are major questions about eventual equipment and
tests
or the laboratory aspects in Kiev. There has been no selection of
boratory
paratus for Kiev as yet.

I would like to have a final decision about the type of lab testing in
Minsk before we schedule a real pilot run. That will not happen before
September so
there is time to get things reorganized. With the changes(or about to be
changes)in the director of the RIRM, it is a good time to reorganize and
streamling the project in Minsk and do the most cost-effective testing
possible.

I have not heard from anyone in NCI since I have been here. Having no
timetable
and no visible plan, I decided to use my time productively. I am still
connected
by email so there should be no problem. If you talk to Elaine Gallin you
can tell her that she can contact me at my email address and I will get it
in Russia.

Regards,

Everett

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----------------- RFC822 Header Follows ------------------
ceived: by quickmail.llnl.gov with SMTP;9 Jul 1996 22:51:52 -0700
Received: by arl-img-2.compuserve.com (8.6.10/5.950515)
     id BAA17606; Wed, 10 Jul 1996 01:51:57 -0400
Date: 10 Jul 96 01:46:44 EDT
From: "Everett K. Mincey" <75324.3526@CompuServe.COM>
To: Sheilah Hendrickson <sheilah.hendrickson@quickmail.llnl.gov>
Subject: Just a small note
Message-ID: <960710054644_75324.3526_EHI58-1@CompuServe.COM>
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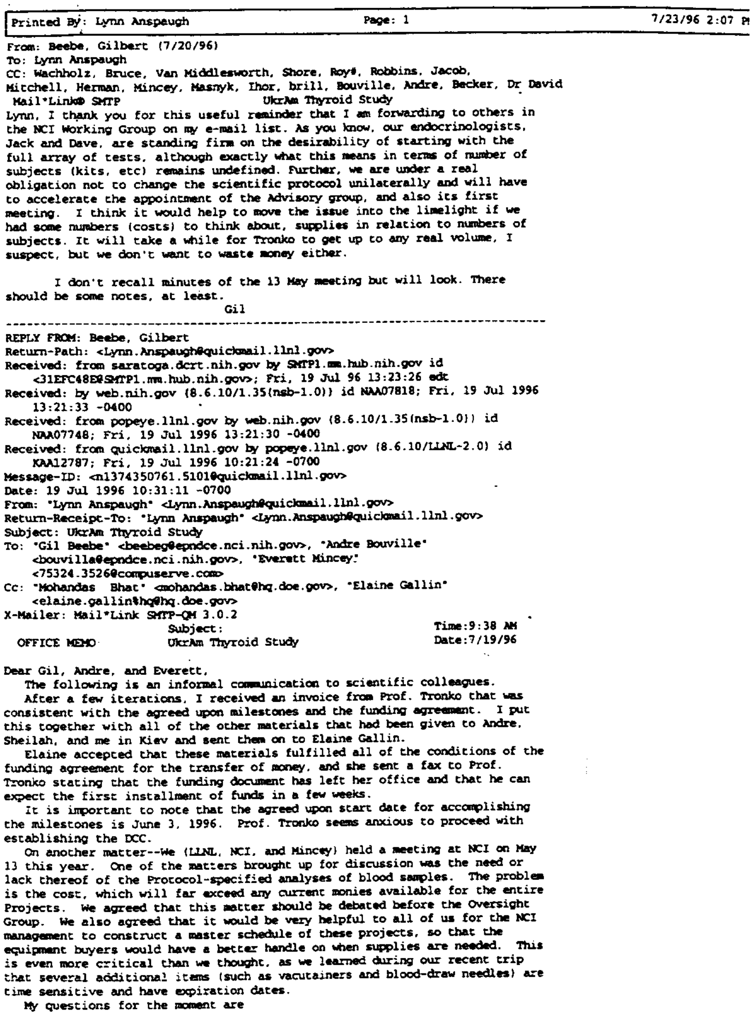

Printed By: Lynn Anspaugh Page: 1 7/23/96 2:07 P

From: Beebe, Gilbert (7/20/96)
To: Lynn Anspaugh
CC: Wachholz, Bruce, Van Middlesworth, Shore, Roy#, Robbins, Jacob,
Mitchell, Herman, Mincey, Masnyk, Ihor, brill, Bouville, Andre, Becker, Dr David
Mail*Link® SMTP UkrAm Thyroid Study

Lynn, I thank you for this useful reminder that I am forwarding to others in the NCI Working Group on my e-mail list. As you know, our endocrinologists, Jack and Dave, are standing firm on the desirability of starting with the full array of tests, although exactly what this means in terms of number of subjects (kits, etc) remains undefined. Further, we are under a real obligation not to change the scientific protocol unilaterally and will have to accelerate the appointment of the Advisory group, and also its first meeting. I think it would help to move the issue into the limelight if we had some numbers (costs) to think about, supplies in relation to numbers of subjects. It will take a while for Tronko to get up to any real volume, I suspect, but we don't want to waste money either.

I don't recall minutes of the 13 May meeting but will look. There should be some notes, at least.

Gil

REPLY FROM: Beebe, Gilbert
Return-Path: <Lynn.Anspaugh@quickmail.llnl.gov>
Received: from saratoga.dcrt.nih.gov by SMTP1.mm.hub.nih.gov id
    <31EFC48E@SMTP1.mm.hub.nih.gov>; Fri, 19 Jul 96 13:23:26 edt
Received: by web.nih.gov (8.6.10/1.35(nsb-1.0)) id NAA07818; Fri, 19 Jul 1996
    13:21:33 -0400
Received: from popeye.llnl.gov by web.nih.gov (8.6.10/1.35(nsb-1.0)) id
    NAA07748; Fri, 19 Jul 1996 13:21:30 -0400
Received: from quickmail.llnl.gov by popeye.llnl.gov (8.6.10/LLNL-2.0) id
    KAA12787; Fri, 19 Jul 1996 10:21:24 -0700
Message-ID: <n1374350761.5101@quickmail.llnl.gov>
Date: 19 Jul 1996 10:31:11 -0700
From: "Lynn Anspaugh" <Lynn.Anspaugh@quickmail.llnl.gov>
Return-Receipt-To: "Lynn Anspaugh" <Lynn.Anspaugh@quickmail.llnl.gov>
Subject: UkrAm Thyroid Study
To: "Gil Beebe" <beebeg@epndce.nci.nih.gov>, "Andre Bouville"
    <bouvilla@epndce.nci.nih.gov>, "Everett Mincey"
    <75324.3526@compuserve.com>
Cc: "Mohandas Bhat" <mohandas.bhat@hq.doe.gov>, "Elaine Gallin"
    <elaine.gallin%hq@hq.doe.gov>
X-Mailer: Mail*Link SMTP-QM 3.0.2

	Subject:	Time:9:38 AM
OFFICE MEMO	UkrAm Thyroid Study	Date:7/19/96

Dear Gil, Andre, and Everett,

The following is an informal communication to scientific colleagues.

After a few iterations, I received an invoice from Prof. Tronko that was consistent with the agreed upon milestones and the funding agreement. I put this together with all of the other materials that had been given to Andre, Sheilah, and me in Kiev and sent them on to Elaine Gallin.

Elaine accepted that these materials fulfilled all of the conditions of the funding agreement for the transfer of money, and she sent a fax to Prof. Tronko stating that the funding document has left her office and that he can expect the first installment of funds in a few weeks.

It is important to note that the agreed upon start date for accomplishing the milestones is June 3, 1996. Prof. Tronko seems anxious to proceed with establishing the DCC.

On another matter--We (LLNL, NCI, and Mincey) held a meeting at NCI on May 13 this year. One of the matters brought up for discussion was the need or lack thereof of the Protocol-specified analyses of blood samples. The problem is the cost, which will far exceed any current monies available for the entire Projects. We agreed that this matter should be debated before the Oversight Group. We also agreed that it would be very helpful to all of us for the NCI management to construct a master schedule of these projects, so that the equipment buyers would have a better handle on when supplies are needed. This is even more critical than we thought, as we learned during our recent trip that several additional items (such as vacutainers and blood-draw needles) are time sensitive and have expiration dates.

My questions for the moment are

1. Are there any minutes of the May 13 meeting? If not, I will prepare.
2. Has anything been done to address the blood-analyses issue? If not, I will start to do so.
3. Is there any movement to appoint an Oversight Group?
4. Has anything been done to construct the master schedule?

Regards, Lynn

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------------------ RFC822 Header Follows ------------------
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Received: from SMTP2.mm.hub.nih.gov by web.nih.gov (8.6.10/1.35(nsb-1.0))
 id LAA19676; Sat, 20 Jul 1996 11:04:08 -0400
Received: by SMTP2.mm.hub.nih.gov with Microsoft Mail
 id <31F0F566@SMTP2.mm.hub.nih.gov>; Sat, 20 Jul 96 11:04:06 edt
From: "Beebe, Gilbert" <BEEBEG@epndce.nci.nih.gov>
To: Lynn.Anspaugh@quickmail.llnl.gov
Cc: "Wachholz, Bruce" <WACHHOLB@epndce.nci.nih.gov>,
        Van Middlesworth <lvanmid@physid.utmem.edu>,
        "Shore, Roy#" <shorer01@mcgc16.med.nyu.edu>,
        "Robbins, Jacob" <JACOBR@BDG10.NIDDK.NIH.GOV>,
        "Mitchell, Herman" <HERMAN%NERI@MCIMAIL.COM>,
        Mincey <75324.3526@compuserve.com>,
        "Masnyk, Ihor" <MasnykI@epndce.nci.nih.gov>,
        brill <brill@umassmed.ummed.edu>
Cc: "Bouville, Andre" <BOUVILLA@epndce.nci.nih.gov>,
        "Becker, Dr David" <BIOPHY@MPCS.MSKCC.ORG>
Subject: UkrAm Thyroid Study
Date: Sat, 20 Jul 96 11:04:00 edt
Message-ID: <31F0F566@SMTP2.mm.hub.nih.gov>
Encoding: 73 TEXT
X-Mailer: Microsoft Mail V3.0


=====================================================================
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Printed By: Lynn Anspaugh Page: 1 7/23/96 2:16 PM

From: Everett K. Mincey (7/19/96)
To: Lynn Anspaugh, Gilbert Beebe, Mohandas Bhat, Andre Bouville,
Elaine Gallin

Mail*Link® SMTP UkrAm Thyroid Study
SUBJECT: Reply to memo of 7/19:

Overview comments---

I am pleased that an agreement has been concluded with principals in Kiev and that they are anxious to start. As you know, I have not been involved at any level with the project in Ukraine so that my understanding of their needs and "wants" with regard to laboratory capability is rudimentary. According to protocol there is provision for in-vitro testing of serum samples. I have noted that on the many "equipment and supplies" lists which have originated with Prof Tronko there have not been budget allowances for supporting items for blood analyses. These would include all phlebotomy items, transport and storage tubes and other items. Support items would be similiar to those for Minsk, but some items may be different if transport requirements are different. As far as I know, no systems for laboratory analysis have been selected as yet.

Specific items-----

1. I have no minutes of the discussions of 13 May although my memory of the general topics is quite good. The major item for the purposes of your memo would be the questions about reducing the variety of in-vitro tests. We, (Jack Robbins, plus others present) could agree that reducing the testing to 3 basic tests for screening would not reduce the scientific nor medical impact of the project but in view of changes to protocols requiring approval of OVERSIGHTcommittee, it is difficult to effect change immediately.

2. I have not heard that the issues about changes in in-vitro testing have been discussed with fretters. It appears to me that in the short term there is little choice but to continue with the protocol. This option is not appealing to me because a certain level of instrumentation and personnel are required for the variety of tests included in the protocol. It would be a fiscal and management burden to gear up for a certain level of testing at the outset and then to reduce it considerably in the future.

3. I cannot speak on this item about Oversight Group.

4. I cannot participate in Master Schedule construction since I have not had direct input in UkrAm project. I have seen copies of various equipment lists, etc but that is about it. If actual testing is going to begin in Ukraine before Belarus we can consider shifting some of the supplies, if logistically feasible. There are many things to consider regarding the laboratory in Ukraine and its operation, not least of which is whether test reagents will be identical to those slated for Belarus so that we can take advantage of savings of volume, whether principals in Ukraine have fixed ideas about kinds of tests(suppliers), for example.

As soon as there is a comprehensive, realistic schedule for Ukraine we can consider how best to meet the deadlines in the most cost effective manner. The one thing we want to avoid is to gear-up for a level and time-frame of testing which is unsuitable, given local conditions and capabilities.

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 id QAA12919; Fri, 19 Jul 1996 16:41:38 -0400
Date: 19 Jul 96 16:39:42 EDT
From: "Everett K. Mincey" <75324.3526@CompuServe.COM>
To: Lynn Anspaugh <lynn.anspaugh@quickmail.llnl.gov>,
        Gilbert Beebe <beebeg@epndce.nci.nih.gov>,
        Mohandas Bhat <mohandas.bhat@hq.doe.gov>,
        Andre Bouville <bouvilla@epndce.nci.nih.gov>,
        Elaine Gallin <elaine.gallin%hq@hq.doe.gov>
Subject: UkrAm Thyroid Study
Message-ID: <960719203942_75324.3526_EHI106-1@CompuServe.COM>
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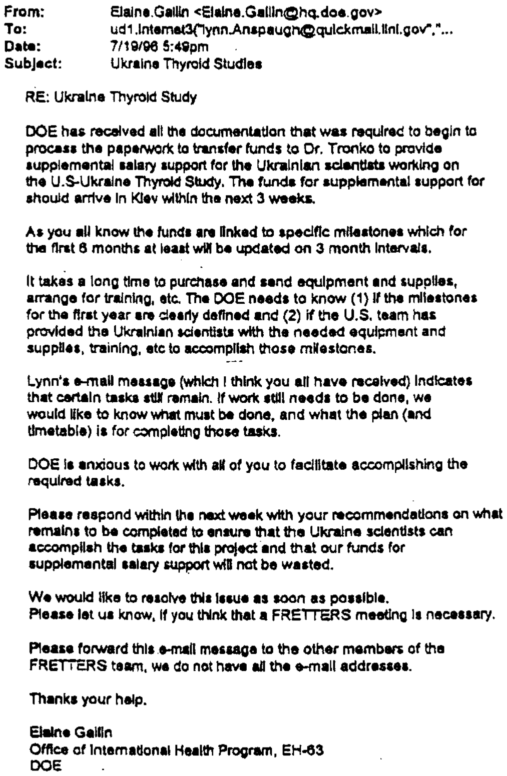

From: Elaine.Gallin <Elaine.Gallin@hq.doe.gov>
To: ud1.Internet3("lynn.Anspaugh@quickmail.llnl.gov","...
Date: 7/19/96 5:49pm
Subject: Ukraine Thyroid Studies

RE: Ukraine Thyroid Study

DOE has received all the documentation that was required to begin to process the paperwork to transfer funds to Dr. Tronko to provide supplemental salary support for the Ukrainian scientists working on the U.S-Ukraine Thyroid Study. The funds for supplemental support for should arrive in Kiev within the next 3 weeks.

As you all know the funds are linked to specific milestones which for the first 6 months at least will be updated on 3 month intervals.

It takes a long time to purchase and send equipment and supplies, arrange for training, etc. The DOE needs to know (1) if the milestones for the first year are clearly defined and (2) if the U.S. team has provided the Ukrainian scientists with the needed equipment and supplies, training, etc to accomplish those milestones.

Lynn's e-mail message (which I think you all have received) indicates that certain tasks still remain. If work still needs to be done, we would like to know what must be done, and what the plan (and timetable) is for completing those tasks.

DOE is anxious to work with all of you to facilitate accomplishing the required tasks.

Please respond within the next week with your recommendations on what remains to be completed to ensure that the Ukraine scientists can accomplish the tasks for this project and that our funds for supplemental salary support will not be wasted.

We would like to resolve this issue as soon as possible.
Please let us know, if you think that a FRETTERS meeting is necessary.

Please forward this e-mail message to the other members of the FRETTERS team, we do not have all the e-mail addresses.

Thanks your help.

Elaine Gallin
Office of International Health Program, EH-63
DOE

Dose Reconstruction Program

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

Address List for Fax dated August 9, 1996

Dr. Ihor Maznyk
Dr. André Bouville
NCI
Fax: 301-496-1224

Dr. Shlomo Yaniv
NRC
Fax: 301-415-5385

Dr. David Becker
New York Hospital
Cornell Medical Center
Fax: 212-746-8873

Dr. Gilbert Beebe
NCI
Fax: 301-496-1854

Dr. A. Bertrand Brill
University of Massachusetts
Medical Center
Fax: 508-856-4572

Dr. Jack Robbins
National Institute of Diabetes and
Digestive and Kidney Diseases
Fax: 301-402-0387

Dr. Elaine Gallin
Dr. Mohandas Bhat
Mr. Frank Hawkins
DOE/EH-63
Fax: 301-903-1413

Dr. Roy Shore
New York University Medical
Center
Fax: 212-263-8570

Dr. Lester Van Middlesworth
University of Tennessee at
Memphis
Fax: 901-448-7126

Dr. Jan Wolff
National Institute of Diabetes and
Digestive and Kidney Diseases
Fax: 301-402-0240

Dr. Everett Mincey
Cymbeline Enterprises LTD.
Fax: 604-888-0471

Dr. Herman Mitchell
New England Research Institute
Fax: 617-926-8246

We are transmitting 8 pages (including cover sheet).

Atmospheric and Ecological Sciences
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Lawrence Livermore National Laboratory, P.O. Box 808, L-286, Livermore, CA 94551-9900
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Fax (510) 424-6408
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Dose Reconstruction Program

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hendrickson3@llnl.gov

EQUIPMENT AND SUPPLY BUDGET

12-MONTH COST ESTIMATE

	BELARUS k$	UKRAINE k$
DOE Capital Equipment Funds (FY 96)	125.7	125.7
Cost including liens through July	78.7	119.5
FUNDS AVAILABLE	**47.0**	**6.2**
NRC Funds (FY 96)	265.2	500.0
Cost including liens through July	95.3	58.2
FUNDS AVAILABLE	**169.7**	**441.8**
TOTAL FUNDS AVAILABLE	**216.7**	**448.0**
12-Month Estimate for E & S Requests Not including cost for test kits	209.4	732.4
Total Funds Available minus Estimate	**7.3**	**-284.4**
First year's costs for clinical chemistry according to the Protocol specifications	142.7	1281.8
The Bottom Line	**-135.7**	**-1,566.2**

As noted above, there is a shortfall of about $2,000,000 for supplies and equipment in order to implement the first 12 months of the projects according to the Protocols and according to the equipment and supply lists that have been received at LLNL. (Note: NCI has approved only a small portion of the requested equipment and has not asked that test kits, other supplies, and equipment be purchased for the performance of clinical chemistry analyses.) Clearly, some cost containment is in order, both in terms of scaling back the equipment requests and in reducing the clinical chemistry tests as stated in the Protocols. (Please refer to a separate fax from Lynn Anspaugh on the clinical chemistry issue.)

Following are four pages that show the breakdown by country and group for the equipment and supply requests for the first twelve months (in the case of Ukraine and the next twelve months for Belarus). We will send via mail (there are too many pages to fax) the requests from each country, group, and justifications for equipment.

Belarus

From DOE and NCI (I recall being told by NCI that discussions took place with people in Belarus regarding this matter), I need a clear understanding of what the "administrative" part of funding support is to cover as far as equipment, supplies, services, and equipment maintenance are concerned. For example, we have specifically advised that LLNL will no longer cover expenses for e-mail services once the funding agreement was in place and they received monies.

Ukraine

Again, from DOE and NCI I need a clear understanding of what the "administrative" part of the funding support is to cover. Thus far, I have explained our business practices in Belarus (regarding e-mail, etc.) or types of items we will or will not purchase and the Ukrainians seem to be receptive Although we have already begun some purchasing activities for Ukraine, we are now at the same point for the equipment and supply process where I was asked to join the activities of the FRETTERS for the purchase of equipment and supplies for the Belarus thyroid protocol. At that time a meeting was convened by NCI (FRETTERS, Mincey, Mitchell, and Hendrickson) where I received several E & S lists from various American team members; the wish list from Belarussians and Russians (via Americans); and decisions were made for phase 1 and phase 2 purchases, the "on hold" listing, and additions and deletions of items. From that point, I was then able to work with individuals for the specifications of required equipment.

As indicated above, I believe it is time for the American team to convene a meeting to review, discuss, and decide on the requested equipment for Ukraine and discuss the plan of action for Belarus. This is especially important, as we have not received (as requested at our May 13 meeting at NCI) a project-implementation schedule with indications of required equipment delivery for both projects. As I am neither a scientist nor a medical person, information, education, and guidance from various American team members for the Ukraine project is needed so that I can perform and fulfill my part of this project.

I request clarification of "administrative" funding support from DOE and NCI and request a response from NCI regarding the above mentioned meeting.

Sheilah Hendrickson LRA

Sheilah Hendrickson

Cost estimates for equipment and supplies for the thyroid protocols for the next 12 months

UKRAINE					
Group / Page	General E & S Description	Page Cost	Subtotal for Group	Total All Groups	Comments
2 Vehicles		65,000.00	65,000.00		1 Vehicle in process of being purchased ($32 K)
Data Coordinating Center / Project Office					
Estimate based on Belarus plus inflation		175,000.00			Somewhat of a wild guess!
	Copier, paper	6,800.00			In process of being purchased
	Fax, air/heat, telephones	6,210.00			In process of being purchased
Subtotal			188,010.00		
Central Laboratory					
First 3 months					
Page 1	Ultrasonic diagnostics	69,310.00			Not including cost of items already purchased
Page 2	Diagnostic, aspiration				
	biopsy & transportation	15,421.00			Not including estimate for 2 portable freezers
Page 3	Analyzer, Kits for blood				or costs of items already purchased
	hormones	0.00			See Anspaugh/Hendrickson test kits estimate
Page 4	Cytology Equipment	1,312.00			Not including est for 4-head microscope
Page 5	Reagents for cytology				
	& immunocytochemistry	933.00			
Page 6	Same as above	502.00			
Next 9 months					
Page 7	Ultrasound 140A	196,983.00			Not including the "unknown amount" of LLNL discount
Page 8	Ultrasonic dia & blood sam	10,510.00			Not including TSH kits--see Anspaugh/Hendrickson list
Page 9	Analyzer, kits for blood				
	hormones	0.00			See Anspaugh/Hendrickson test kits estimate
Subtotal			294,971.00		

Cost estimates for equipment and supplies for the thyroid protocols for the next 12 months

Pathology Laboratory					
12 months					
Page 10	Measurement Equipment	13,569.00			
Page 11	Supplies, chemicals	6,034.00			
Page 12	Chemicals	20,046.00			
Page 13	Supplies, chemicals	16,860.00			
Page 14	Equipment, supplies	1,979.00			
Page 15	Equipment, supplies	62,734.00			Includes costs for Photomicroscope with computer system ($55 K)
Page 16	Slide stainer, slide project				
	computer, notebook,				
	scanners, printer	11,578.00			
Page 17	Copier, books	4,300.00			Not including costs for items already purchased
Page 18	Film, photopaper	1,500.00			
Page 19	Kodak developer, photo				
	paper, fix agent	unk			
	Computer upgrade,				
	modem, printer	1,750.00			Already purchased.
Subtotal			140,350.00		
Dosimetry and Risk Analysis / Ukraine Radiation Protection Institute					
	Computers, software	41,000.00			
	Fax, air conditioner,	2,410.00			
	Chairs, office supplies	700.00			Guesstimate.
Subtotal			44,110.00		
Total All Groups				732,441.00	

Cost estimates for equipment and supplies for the thyroid protocols for the next 12 months

BELARUS					
Group / Page	General E & S Description	Page Cost	Subtotal for Group	Total All Groups	Comments
Data Coordinating Center / Project Office					
Page 20	Computer, upgrade, paper	5,827.00			
Page 21	Bar Code Labels for tubes				Currently do not have estimate
Subtotal			5,827.00		
Epidemiology					
Page 22	Computer, Copier	3,586.00			
Subtotal			3,586.00		
Central Laboratory					
Page 23	Chemicals	150.00			Does not incl test kits. See Anspaugh/Hendrickson test kits est.
Page 24	Chemicals	269.00			Does not incl test kits. See Anspaugh/Hendrickson test kits est.
Page 25	Vacutainers, needles, orbital shaker, flasks, beakers. etc	2,656.00			
Page 26	Equipment/supplies	1,037.00			Does not incl $524 for multi timer already purchased.
Subtotal			4,112.00		
Screening Center					
Page 27	Thermal paper/ultrasound	1,200.00			
	Diskettes	10.00			
Subtotal			1,210.00	14,735.00	
Moscow Dosimetry					
Page 28	Computer, upgrade, note-book, printer, supplies	26,705.00			
Subtotal			26,705.00	26,705.00	
Total Belarus / Moscow				41,440.00	

Cost estimates for equipment and supplies for the thyroid protocols for the next 12 months

Items to purchase from LLNL Spreadsheet Database					
	Second Ultrasound 250A	84,900.00			
	Air Conditioner	1,600.00			Only if needed for new building
	2 Vehicles	65,000.00			
	Computer, office equipment, blinds	7,000.00			Project Office-Pending new building
	Partitions	2,000.00			Screening Center/DCC/Project Office
	Soap	unk			Screening Center (Need specifications)
	Laboratory Mgmt Software	6,500.00			Requested by Everett Mincey
	File cabinets (duplicate patient info)	1,000.00			DCC (guess estimate unknown specifications)
			168,000.00	168,000.00	
Total Belarus/Moscow + LLNL				209,440.00	

Dose Reconstruction Program

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Cymbeline Enterprises LTD.
Fax: 604-888-0471

Dr. Herman Mitchell
New England Research Institute
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We are transmitting 7 pages (including cover sheet).

Atmospheric and Ecological Sciences
Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, L-286, Livermore, CA 94551-9900
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August 9, 1996

TO: Addressees on previous page

TELE NO:

FAX NO:

FROM: Lynn Anspaugh

TELE NO: (510) 424-6409

SUBJECT: Costs associated with Clinical Chemistry Tests Indicated in Protocols

MESSAGE: As some of you know, we have been trying to draw attention to the disparity between the amount of money allocated to the thyroid projects and the cost requirements of the two thyroid protocols, particularly as it concerns the prescribed tests for clinical chemistry. This was discussed extensively with approximate estimates of costs during a May 13 meeting at NCI with LLNL, Dr. Robbins, and Dr. Mincey.

Subsequently, Dr. Beebe suggested that it would sharpen the focus if there were more specific cost estimates. These estimates are provided on the following pages to the best of our ability. These materials have been sent to Dr. Robbins and Dr. Mincey for review, but we do not believe that Dr. Mincey has yet seen them. Following the cost estimate sheets are remarks from Dr. Robbins on ways to contain the costs. Presumably, such suggestions would have to be approved by the Oversight Committee, whenever there is one.

As nearly all of you are much more experienced in this business than are we, we would appreciate any comments/suggestions regarding the validity of the cost estimates.

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Environmental Programs Directorate
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Cost estimates for the chemicals required to perform the clinical chemistry studies for the thyroid protocols for Ukraine and Belarus.

Test	Rep-li-cates	Unit cost	Ukraine number*			Ukraine cost		
			Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
Thyroid stimulating hormone (TSH)	2	$ 3.34	24,000	20,000	40,000	$ 160,320	$ 133,600	$ 267,200
Thyroxine (T4)	2	$ 2.75	24,000	20,000	40,000	$ 132,000	$ 110,000	$ 220,000
Free thyroxine (FT4)	2	$ 4.70	24,000	20,000	40,000	$ 225,600	$ 188,000	$ 376,000
Total tri-iodothyronine (T3)	2	$ 4.55	*1,200*	*1,000*	*2,000*	$ 10,922	$ 9,102	$ 18,204
Antithyroid peroxidase (ATPO)	2	$ 2.80	24,000	20,000	40,000	$ 134,400	$ 112,000	$ 224,000
Antithyroglobulin (Anti TG)	2	$ 2.80	1,200	1,000	2,000	$ 6,720	$ 5,600	$ 11,200
Thyroglobulin (TG)	2	$ 2.65	1,200	1,000	2,000	$ 6,360	$ 5,300	$ 10,600
Albumin and Calcium	2	$ 4.98	*24,000*	*20,000*	*40,000*	$ 239,040	$ 199,200	$ 398,400
Vacutainers and needles	1	$ 0.48	25,000	25,000	50,000	$ 12,000	$ 12,000	$ 24,000
Parathyroid hormone	2	$ 2.80	500	400	800	$ 2,800	$ 2,240	$ 4,480
I in urine (inc. U. Mass. meas. cost)	*1*	$ 35.00	*6,000*			$ 210,000	$ -	$ -
Miscellaneous (test tubes, pippettes?)	1	*$ 5.90*	*24,000*	*20,000*	*40,000*	$ 141,600	$ 118,000	$ 236,000
Sum						$ 1,281,762	$ 895,042	$ 1,790,084

*These numbers are taken from the UkrAm Protocol, except for those in italics, which were estimated by LRA.

The protocol states that, "All unknown sera...must be run in duplicate...."

Unit costs are based on contracts placed during 1995 or quotations received in 1996. No allowance has been made for inflation.

Miscellaneous costs are estimated from information contained in the Belarus protocol.

Cost estimates for the chemicals required to perform the clinical chemistry studies for the thyroid protocols for Ukraine and Belarus.

	Rep-li-cates	Unit cost	Belarus number**			Belarus cost		
			Year 1	Year 2	Year 3	Year 1	Year 2	Year 3
Thyroid stimulating hormone (TSH)	2	$ 3.34	3,000	9,000	15,000	$ 20,040	$ 60,120	$ 100,200
Thyroxine (T4)	2	$ 2.75	3,000	450	750	$ 16,500	$ 2,475	$ 4,125
Free thyroxine (FT4)	2	$ 4.70	3,000	9,000	15,000	$ 28,200	$ 84,600	$ 141,000
Total tri-iodothyronine (T3)	2	$ 4.55	150	450	750	$ 1,365	$ 4,096	$ 6,827
Antithyroid peroxidase (ATPO)	2	$ 2.80	3,000	9,000	15,000	$ 16,800	$ 50,400	$ 84,000
Antithyroglobulin (Anti TG)	2	$ 2.80	150	450	750	$ 840	$ 2,520	$ 4,200
Thyroglobulin (TG)	2	$ 2.65	*150*	*450*	*750*	$ 795	$ 2,385	$ 3,975
Albumin and Calcium	2	$ 4.98	3,000	9,000	15,000	$ 29,880	$ 89,640	$ 149,400
Vacutainers and needles	1	$ 0.48	*3,125*	*11,250*	*18,750*	$ 1,500	$ 5,400	$ 9,000
Parathyroid hormone	2	$ 2.80	60	180	300	$ 336	$ 1,008	$ 1,680
I in urine (inc. U. Mass. meas. cost)	*1*	$ 35.00	250	250	500	$ 8,750	$ 8,750	$ 17,500
Miscellaneous (test tubes, pippettes?)	1	*$ 5.90*	*3,000*	*9,000*	*15,000*	$ 17,700	$ 53,100	$ 88,500
Sum						$ 142,706	$ 364,494	$ 610,407

**These numbers are taken from the BelAm Protocol, expect for those in italics, which were estimated by LRA.

The protocol states that, "All unknown sera...must be run in duplicate...."

Unit costs are based on contracts placed during 1995 or quotations received in 1996. No allowance has been made for inflation.

Miscellaneous costs are estimated from information contained in the Belarus protocol.

Cost estimates for the chemicals required to perform the clinical chemistry studies for the thyroid protocols for Ukraine and Belarus.

Total cost for both countries	Year 1	Year 2	Year 3
Ukraine	$ 1,281,762	$ 895,042	$ 1,790,084
Belarus	$ 142,706	$ 364,494	$ 610,407
Total	$ 1,424,468	$ 1,259,536	$ 2,400,491
Comparison to costs indicated in the Protocols	Year 1	Year 2	Year 3
Ukraine (only *numbers* of tests are indicated in Appendix B.2)	Not given	Not given	Not given
Belarus (from Table A.3)	$ 111,705	$ 190,845	$ 333,825
Total	Not calcuable	Not calcuable	Not calcuable

Return-Path: <daemon@pierce.llnl.gov>
Received: from saratoga.dcrt.nih.gov by SMTP3.mm.hub.nih.gov id
<3209FDFE@SMTP3.mm.hub.nih.gov>; Thu, 08 Aug 96 10:47:26 edt
Received: by web.nih.gov (8.6.10/1.35(nsb-1.0)) id KAA05192; Thu, 8 Aug 1996
10:45:05 -0400
Received: from pierce.llnl.gov by web.nih.gov (8.6.10/1.35(nsb-1.0)) id
KAA05169; Thu, 8 Aug 1996 10:45:04 -0400
Received: by pierce.llnl.gov (8.6.10/LLNL-1.18/llnl.gov-03.95) id HAA09419;
Thu, 8 Aug 1996 07:45:04 -0700
Message-Id: <199608081445.HAA09419@pierce.llnl.gov>
From: postmaster@llnl.gov (Automated response from LLNL Postmaster)
Date: Thu, 8 Aug 96 07:45:03 PDT
To: JacobR@bdg10.niddk.nih.gov
Subject: FAILED MAIL to unknown recipient "anspaughl"

Your mail to "anspaughl" could not be delivered because
"anspaughl" is an unknown mail name.

No additional locator information is available at this time.

Original message as received is as follows:

Return-Path: <JacobR@bdg10.niddk.nih.gov>
Received: from web.nih.gov by pierce.llnl.gov
(8.6.10/LLNL-1.18/llnl.gov-03.95)
id HAA09377; Thu, 8 Aug 1996 07:44:52 -0700
Received: from SMTP2.mm.hub.nih.gov by web.nih.gov (8.6.10/1.35(nsb-1.0))
id KAA04739; Thu, 8 Aug 1996 10:44:46 -0400
Received: by SMTP2.mm.hub.nih.gov with Microsoft Mail
id <3209FD5C@SMTP2.mm.hub.nih.gov>; Thu, 08 Aug 96 10:44:44 edt
From: "Robbins, Jacob" <JacobR@bdg10.niddk.nih.gov>
To: "Anspaugh, Lynn" <anspaughl@llnl.gov>
Cc: "Mincey,Everett K." <75324.3526@CompuServ.COM>
Subject: costs for clin chem
Date: Thu, 08 Aug 96 10:44:00 edt
Message-ID: <3209FD5C@SMTP2.mm.hub.nih.gov>
Encoding: 19 TEXT
X-Mailer: Microsoft Mail V3.0

This is in response to your 6 Aug fax. I don't have a copy of the protocol at hand, so this is off the top of my head.

Duplicates should be dispensed with, pending approval by the oversight comm. This got in the protocols before Mincey's expertise got involved.

Total T4 and Free T4 Are both done during the first year, after which only one is continued, preferably Free T4. If budget containment is required, I would eliminate FT4, with oversight comm. approval, and if Mincey agrees. In this case, we would need a certain number of FT4 tests for back-up (~5%).

Urine iodine inclusion depends on whether the EC is proceeding with their plans. The supply requirement can be answered by Mincey and is not great, but equipment cost is substantial.

Please confirm that you receive this, since I'm new at the game. Also, Mincey didn't receive my message the one time I tried.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

National Institutes of Health
National Cancer Institute
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August 13, 1996

Note for Members of the NCI Working Group on Thyroid Studies Following Chernobyl

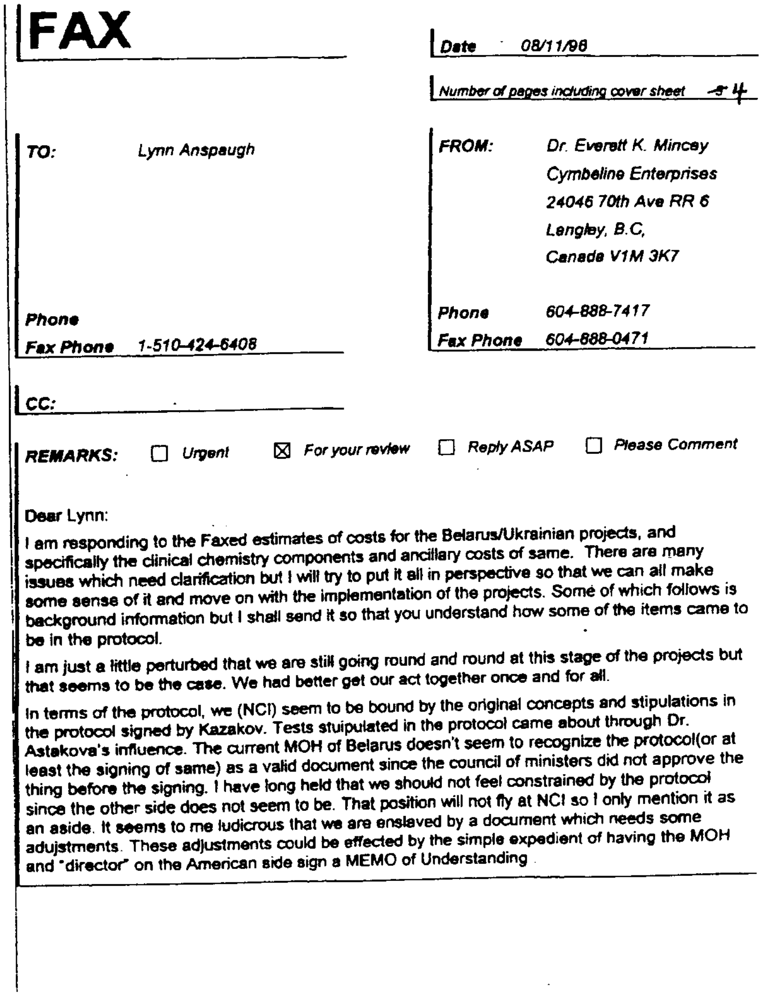
Subject: Transmittal of Dr Mincey's Views on Clinical Chemistry Aspects of the Projects

Since you will already have received copies of Dr Anspaugh's FAX'd messages of 9 August, I thought you might like to have Dr Mincey's analysis of the situation. He has been our advisor on setting up the laboratory in Minsk, as most of you know. There appears to be a clash between the protocol requirements and the funds available. The funds for the laboratory tests may have to be reduced in order to keep costs within the fiscal limits, unless the latter can be modified. As you know, the protocols call for advisory groups that could, at their very first meetings, consider this issue and modify the protocols accordingly if they wish. Meanwhile it seems to me that we need to advise LLNL that the procurement should be provisionally modified pending a decision by the Advisory Groups.

Dr Wachholz is on vacation but I'm sure he would appreciate your thoughts on the situation and any recommendations you have.

Gilbert W. Beebe, PhD

Enclosure



FAX

Date 08/11/98

Number of pages including cover sheet ~~5~~ 4

TO: Lynn Anspaugh

Phone

Fax Phone 1-510-424-6408

FROM: Dr. Everett K. Mincey
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24046 70th Ave RR 6
Langley, B.C,
Canada V1M 3K7

Phone 604-888-7417

Fax Phone 604-888-0471

CC:

REMARKS: ☐ Urgent ☒ For your review ☐ Reply ASAP ☐ Please Comment

Dear Lynn:

I am responding to the Faxed estimates of costs for the Belarus/Ukrainian projects, and specifically the clinical chemistry components and ancillary costs of same. There are many issues which need clarification but I will try to put it all in perspective so that we can all make some sense of it and move on with the implementation of the projects. Some of which follows is background information but I shall send it so that you understand how some of the items came to be in the protocol.

I am just a little perturbed that we are still going round and round at this stage of the projects but that seems to be the case. We had better get our act together once and for all.

In terms of the protocol, we (NCI) seem to be bound by the original concepts and stipulations in the protocol signed by Kazakov. Tests stuipulated in the protocol came about through Dr. Astakova's influence. The current MOH of Belarus doesn't seem to recognize the protocol(or at least the signing of same) as a valid document since the council of ministers did not approve the thing before the signing. I have long held that we should not feel constrained by the protocol since the other side does not seem to be. That position will not fly at NCI so I only mention it as an aside. It seems to me ludicrous that we are enslaved by a document which needs some adujstments. These adjustments could be effected by the simple expedient of having the MOH and "director" on the American side sign a MEMO of Understanding

Since there is no interest at NCI in reopening (or amending) the protocol, it looks as if the only recourse will be with the advisory group.

Now to some of the line items.

1. In terms of evaluating the "thyroid" the tests which are available can be put into three groups.
a. Anatomical/structural—includes ultrasound and radionuclide scanning, as well as palpation.
b. Tests which assess function--includes TSH, T-4, T-3, FT-4
c. Tests which assess autoimmune status--includes Anti-TPO, Anti-thyroglobulin.

All of the other tests on the menu do something else. In terms of the aim of the project, which is to detect thyroid cancer(and other thyroid abnormalities) we need to "screen" with one (or more) of tests in each of these groups.
To cover the protocol the following would be adequate:
1. Palpation and ultrasound
2. TSH
3. Anti-TPO

Albumin and calcium are related to parathyroid pathology. It is of "scientific" interest to detect any parathyroid abnormalities but the incidence will be low(my words) and the screening costs high. Parathyroid hormone assays are to be reserved for only those patients with well documented hypo-and hyper-calcemia. There will not be many in the young population which we have elected to screen as the cohort.
In terms of budgeting, I would delete T-3 entirely, since it is useful only for those patients suspected of having "T-3" toxicosis and then only as a secondary or tertiary test. The need will be so low as to render it a non-item in terms of the budget.
The same could be said for parathyroid hormone assay. The very few which can be worked up and documented properly should have their serum sent to USA or other country for PTH. It is not cost effective to consider doing the assay in either Belarus or Ukraine. The assay is not particularly easy and one needs a laboratory with years of experience in PTH to properly interpret the test results.

With regard to urinary iodine, the decision to do any or not is still up in the air as far as I know. Lets take the worst case, If we decide to do them, they will be done locally, not sent to the USA. In addition, equipment to do urinary iodines is already in place in Minsk. The cost of doing the assay is minimal once the equipment is in place. I would suggest that you reduce the disposables cost to $ 0.50 per assay(not $25.00) I do not know what the situation will be in Ukraine but certainly do not budget 25.00 for the assays.

With regard to the line items for miscellaneous(test tubes, pipettes, etc there seems to be a discrepancy in the "unit cost" between Belarus and Ukraine. Why would one be 1.00 and the other 5.90? These items are related to one venipuncture and include take-off tubes, storage tubes and transfer pipettes. I don't see why it should be any different. Furthermore, test tubes and transfer pipettes cost only pennies each. Consider that we may use 5 or 6 tubes per patient and a transfer pipette or two, the estimated cost should be between 0.50 and 1.00 for each patient encounter(i.e., unit cost).

This still leaves us with some unresolved questions about the clinical chemistry. The following scenarios may ensue, depending on whether the advisory group can meet soon.

SCENARIO-1

Decide to do only TSH as the prime screening test for function. Do T-4 as the secondary test. I would estimate that only 10% of the total tested with TSH would need a secondary test(probably only 5%)

Do only Anti-TPO as the screening test for autoantibodies.

Have T-4 and antithyroglobulin as second line tests and budget for about 5-10% of the cohort. Do not do FT-4 in any circumstance. If any patient is found to be hyper or hypo thyroid by TSH assay and by clinical impression they will fall into the local system for further evaluation and treatment in which case the secondary tests may be done within the health care system of the country. Why do we need to do them also? It is sufficient that we spot these persons--clinical impression and a TSH assay are sufficient to do that. Any more tests of thyroid function for screening essentially well patients is a waste of money and time.

Do not do albumin and calcium at all.

Do not do T-3 in any case. Do not do anti-thyroglobulin in any case.

SCENARIO-2

Screen with TSH and have T-4 as secondary test. Do calcium and albumin on every patient. Do Thyroglobulin only on those patients who have suspicious anatomical findings. Do anti-thyroglobulin on those having significant titres of anti-TPO. Do not do PTH locally in any case. Do not do T-3 in any case.

SCENARIO-3

Do function tests as outlined in your line item list. It is a waste of money and effort to do three screening tests of thyroid function on essentially well(as far as function is concerned) populations but if there is no way to escape the protocol then we are stuck. In any event we do not need to do PTH locally, nor do we need to plan to do T-3. Reduce the cost of urinary iodine to between 0.50 and 1.00 per assay.

The cost in the line item for albumin and calcium is for both tests I believe (roughly 2.50 each) so is not out of line.

In view of the extraordinary cost of the clinical chemistry testing protocols on each patient it would seem to be prudent to try to assemble an advisory committee as soon as possible to try to reduce the amount of testing on serum to a medical and scientific minimum. In theory we could eliminate it altogether in terms of cancer detection, but no one would want to do that since we will have a captive cohort and it is valid to assess function as well for the sake of completeness. We can assess function but in a more cost-effective manner than is called for in the protocol.

I don't know how we are going to resolve these disagreements and bring the entire budget into line with what funds are available.

cc: Jack Robbins

Dose Reconstruction Program

(Former Risk Sciences Center)

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August 13, 1996

TO: André Bouville
Lynn Anspaugh

FROM: Sheilah Hendrickson **TELE NO:** (510) 424-6410

André and Lynn: Hi André!

Following: (1) August 8 e-mail to Tronko and Bogdanova, and
(2) Draft letter to Tronko and Likhtarev

During our visit I told Dr. Tronko I would provide him a copy of the cost estimate once I received all requests from all groups. I plan to send him Pages 1 and 2 (Ukraine only) of my spreadsheet and not the written narrative (fax dated August 9th). I will also send the 19 pages of equipment and supply requests received from Ukraine that contains our notations of estimated costs. André, Pages 1 through 19 were sent to you and the other American team members today by Express Mail. You should receive this within the next couple days.

I plan to send the above to Tronko by Federal Express on August 15th. Do either of you have any concerns, suggestions, or changes to my draft letter to Tronko and Likhtarev?

Sheilah

We are transmitting 4 pages (including this cover sheet).

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program
Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-453, Livermore, CA 94551-9900
University of California
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Printed By: Sheilah Hendrickson 8/8/96 2:59 PM
Page: 1
From: Sheilah Hendrickson (8/8/96)
To: Tatyana Bogdanova
CC: Lynn Anspaugh
BCC:
Priority: Normal
Date sent: 8/8/96 2:59 PM

OFFICE MEMO

Subject: Several

Time: 1:58 PM

Date: 8/8/96

Dear Dr. Tronko and Dr. Bogdanova:

I have read Dr. Bogdanova's 2 faxes dated August 1; Dr. Tronko's fax to Lynn Anspaugh dated August 1, and the fax from Zeiss dated August 1. In reading all these more carefully, I am sorry to report that I must ask you to resend the quotations from Zeiss. Some of the line items can not be read.

I am in the process of putting all the requests for equipment and associated estimated costs for the entire project together and hope to present this information to both the Americans and Ukrainians shortly. There are several items already in process or about to be processed for purchase (fax and copy machines, air conditioners, paper, vehicle, computers for Sobolev's Group, etc.). I also hope to begin some of the purchasing of Dr. Bogdanova chemicals next week as well.

However, if Lynn and I are corect, our preliminary estimations indicate that all equipment requests that I have received plus the test kits required for the first year (per the protocol) far exceeds the amount of funding we have for equipment and supplies. I am sure that some very hard decisions will need to be made from both sides. Again, I will be sending more detailed information regarding this matter to the Americans and Ukrainians soon.

With my best regards,
Sheilah Hendrickson

Dose Reconstruction Program
(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

August 14, 1996

Draft

Prof. Nikolai Tronko
Project Director

Prof. Ilya Likhtarev
Deputy Project Director

REGARDING: Equipment and Supplies for

"Scientific Protocol of Thyroid Cancer and Other Thyroid Disease in Ukraine Following the Chernobyl Accident"

Dear Prof. Tronko:

Per my August 8, 1996 e-mail, I am enclosing the 12-month cost estimates for the equipment and supplies. This is based on the requests I received from all groups.

As you can see, the total amounts to approximately $732,441. This amount does not include the approximate costs for clinical chemistry for the first year. As you know, the total amount of funds we have available for purchasing all of these items is $625,700. This information has also been sent to the American team and is currently under review. The clinical tests and associated costs is of primary concern and is also currently being discussed. I might point out (as in the case with Belarus) that this list and cost estimate does not include items that were jointly identified and deemed necessary for various parts of the study (laboratory set-up or process, DCC, etc.) nor does this include equipment and supplies for the mobile teams.

During our visit to Ukraine, Dr. André Bouville and I spoke with the Anna Karaoglou from the European Commission (EC). She told me the equipment they were supplying to the Ukraine had been ordered and should start to arrive around the beginning of August. It would be very helpful if you can notify me by e-mail, the item or items you receive from the EC (including the group receiving) that can be eliminated for purchase by the U.S. Also, please notify me if quantities of any items should be lowered on the U.S. list (due to you receiving some quantity from the EC). I believe the best way is to

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identify the page number (number on the right lower corner with a circle around it) and the item number. I might add that Dr. Bogdanova already offered to notify me what items she receives from the EC and can be eliminated from our list for the Pathology Laboratory.

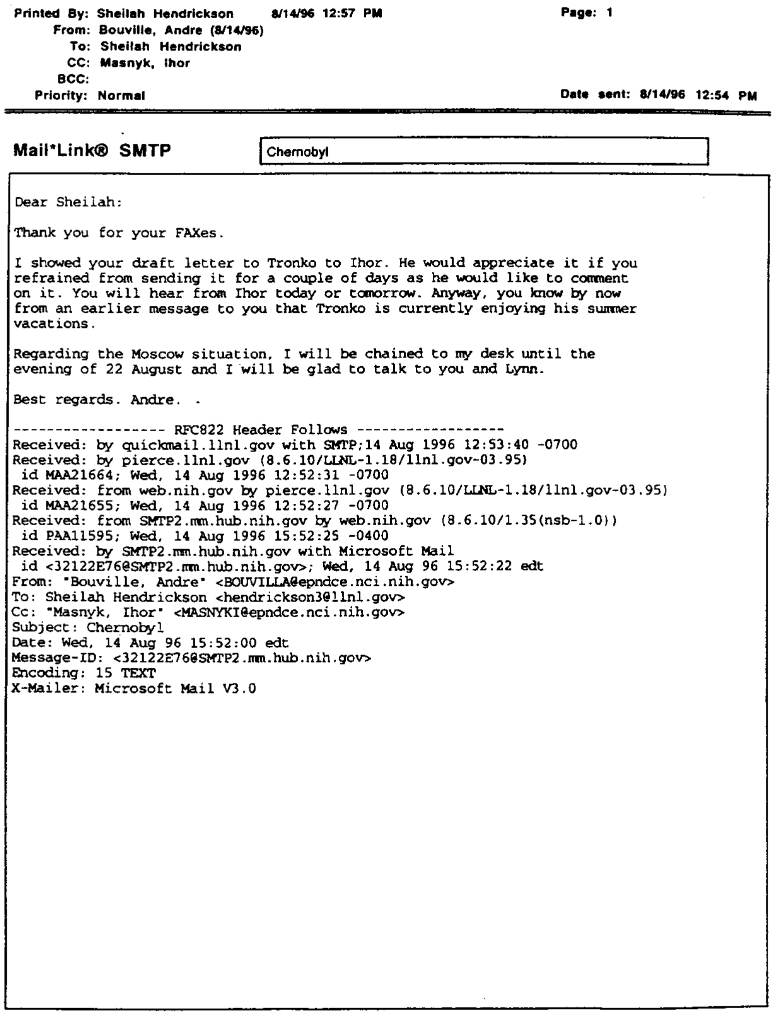
I realize the equipment forms that we requested and received is for the first 12 months of the project, but it is obvious the costs are more than the available funds. As I stated in my fax dated August 8, some very hard decisions will need to be made from both sides. Perhaps you and your staff can carefully review each group's requests and suggest to us what items can be moved to year 2 without impacting the first 12 months of the study.

I look forward to hearing from you soon. Please contact me, if you have any questions or need further clarification.

Sincerely,

Sheilah Hendrickson
Project Manager
Equipment and Supplies

Copies:
Lynn Anspaugh
André Bouville
Randy Brill
Elaine Gallin



Printed By: Sheilah Hendrickson 8/14/96 12:57 PM **Page:** 1
From: Bouville, Andre (8/14/96)
To: Sheilah Hendrickson
CC: Masnyk, Ihor
BCC:
Priority: Normal **Date sent:** 8/14/96 12:54 PM

Mail*Link® SMTP Chernobyl

Dear Sheilah:

Thank you for your FAXes.

I showed your draft letter to Tronko to Ihor. He would appreciate it if you refrained from sending it for a couple of days as he would like to comment on it. You will hear from Ihor today or tomorrow. Anyway, you know by now from an earlier message to you that Tronko is currently enjoying his summer vacations.

Regarding the Moscow situation, I will be chained to my desk until the evening of 22 August and I will be glad to talk to you and Lynn.

Best regards. Andre. .

```
------------------ RFC822 Header Follows ------------------
Received: by quickmail.llnl.gov with SMTP;14 Aug 1996 12:53:40 -0700
Received: by pierce.llnl.gov (8.6.10/LLNL-1.18/llnl.gov-03.95)
 id MAA21664; Wed, 14 Aug 1996 12:52:31 -0700
Received: from web.nih.gov by pierce.llnl.gov (8.6.10/LLNL-1.18/llnl.gov-03.95)
 id MAA21655; Wed, 14 Aug 1996 12:52:27 -0700
Received: from SMTP2.mm.hub.nih.gov by web.nih.gov (8.6.10/1.35(nsb-1.0))
 id PAA11595; Wed, 14 Aug 1996 15:52:25 -0400
Received: by SMTP2.mm.hub.nih.gov with Microsoft Mail
 id <32122E76@SMTP2.mm.hub.nih.gov>; Wed, 14 Aug 96 15:52:22 edt
From: "Bouville, Andre" <BOUVILLA@epndce.nci.nih.gov>
To: Sheilah Hendrickson <hendrickson3@llnl.gov>
Cc: "Masnyk, Ihor" <MASNYKI@epndce.nci.nih.gov>
Subject: Chernobyl
Date: Wed, 14 Aug 96 15:52:00 edt
Message-ID: <32122E76@SMTP2.mm.hub.nih.gov>
Encoding: 15 TEXT
X-Mailer: Microsoft Mail V3.0
```

15 Aug 96

Sheilah:

A number of memoranda crossed my desk recently concerning procurement of equipment for the thyroid project in Kyiv. I am slightly worried that we do not overspend now at the time when we get all these signals that there is not enough to cover all the requests.

We had our meeting in May and reached some decisions what to purchase for Dr. Tronko's group and what to table for the time-being; Dr. Wachholz approved our list as he did the addition of a number of chemicals for Dr. Bogdanova. I believe this was the extent of our decision. I would like to see that we do not exceed it without a persuasive reason and then only after a thorough review by NCI staff and specific approval for all additions.

In one of your listings, I came across 5 pathology text books for Dr. Bogdanova which surprised me: where did this come from? Along with it came quotations for a microscope with camera attachments; again I do not recall having this approved before. I believe that it would be best to stick with our decisions made in May. Until the situation with EC equipment delivery is cleared up, the requests from Dr. Bogdanova must be tabled; we will review her needs again at some future time, after all the EC equipment has arrived or failed to. As you and Dr. Anspaugh pointed out recently "the requests exceed the available funds" and "some very hard decisions must be made". Therefore, please, for present let us abide by the decisions made in May.

In line with these concerns, I have seen a copy of the letter you plan to send to Drs. Tronko and Likhtarev. You are perfectly correct in trying to facilitate procurement of the needed equipment and, although I find nothing objectionable in the text, I feel that the information you seek to obtain from them (especially from Dr. Bogdanova) should be channeled through NCI. After all, we will have to make the ultimate decision of what to approve for procurement and, like you, we need to stay on top of all these developments. I hope you will not mind modify your text slightly in line with this observation.

Ihor

P.S. In all this paper storm, I do not recall whether I have sent you a copy of the minutes of the May session. To make sure that I did, I attach them now.

Dose Reconstruction Program

(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

August 20, 1996

TO: Ihor Masnyk

TELE NO:		FAX NO:	301-496-1224
FROM:	Sheilah Hendrickson	TELE NO:	(510) 424-6410

We are transmitting ~~33~~ 4 pages (including this cover sheet).

Health and Ecological Assessment Division
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Ihor:

Following is my "revised" letter to Drs. Tronko and Likhtarev. I eliminated the third paragraph completely regarding equipment from the EC. The last sentence in the new Paragraph 3 has been replaced with ***In line with this concern, the Project Director, Ihor Masnyk, from the National Cancer Institute will be in contact with you soon.***

I believe it would be best for you to directly communicate with Dr. Tronko regarding information you wish to have channeled through NCI, thus avoiding any one that could imply, perceive, interpret or infer that I or LLNL was speaking for NCI.

Sheilah

Sheilah Hendrickson

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(Former Risk Sciences Center)

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August 20, 1996

Prof. Nikolai Tronko
Project Director

Prof. Ilya Likhtarev
Deputy Project Director

REGARDING: Equipment and Supplies for

"Scientific Protocol of Thyroid Cancer and Other Thyroid Disease in Ukraine Following the Chernobyl Accident"

Dear Profs. Tronko and Likhtarev:

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As you can see, the total amounts to approximately $732,441. This amount does not include the approximate costs for clinical chemistry for the first year. As you know, the total amount of funds we have available for purchasing all of these items is $625,700. This information has also been sent to the American team and is currently under review. The clinical tests and associated costs are of primary concern and are also currently being discussed. I might point out (as in the case with Belarus) the Ukraine list and cost estimate does not include items that may be jointly identified and deemed necessary for various parts of the study (laboratory set-up or process, DCC, etc.) nor does this list include equipment and supplies for the mobile teams.

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It is obvious the costs for the requested equipment from your staff for the first 12 months of the project are more than the available funds. As I stated in my fax dated August 8, some very hard decisions will need to be made from both sides. In line with this concern, the Project Director, Ihor Masnyk, from the National Cancer Institute will be in contact with you soon.

Please contact me, if you have any questions or need further clarification regarding the enclosures.

Sincerely,

Sheilah Hendrickson
Project Manager
Equipment and Supplies

Enclosures
- Nikolai Tronko (2)
- Ilya Likhtarev (1)

Copies without enclosures:
- Lynn Anspaugh
- Mohandas Bhat
- André Bouville
- Randy Brill
- Elaine Gallin
- Ihor Masnyk

Dose Reconstruction Program
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August 20, 1996

Prof. Nikolai Tronko
Project Director

Prof. Ilya Likhtarev
Deputy Project Director

REGARDING: Equipment and Supplies for

"Scientific Protocol of Thyroid Cancer and Other Thyroid Disease in Ukraine Following the Chernobyl Accident"

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Please contact me, if you have any questions or need further clarification regarding the enclosures.

Sincerely,

Sheilah Hendrickson

Sheilah Hendrickson
Project Manager
Equipment and Supplies

Enclosures
- Nikolai Tronko (2)
- Ilya Likhtarev (1)

Copies without enclosures:
- Lynn Anspaugh
- Mohandas Bhat
- André Bouville
- Randy Brill
- Elaine Gallin
- Ihor Masnyk

Cost estimates for equipment and supplies for the thyroid protocols for the next 12 months

UKRAINE					
Group / Page	General E & S Description	Page Cost	Subtotal for Group	Total All Groups	Comments
2 Vehicles		65,000.00	65,000.00		1 Vehicle in process of being purchased ($32 K)
Data Coordinating Center / Project Office					
Estimate based on Belarus plus inflation		175,000.00			Somewhat of a wild guess!
	Copier, paper	6,800.00			In prócess of being purchased
	Fax, air/heat, telephones	6,210.00			In process of being purchased
Subtotal			188,010.00		
Central Laboratory					
First 3 months					
Page 1	Ultrasonic diagnostics	69,310.00			Not including cost of items already purchased
Page 2	Diagnostic, aspiration biopsy & transportation	15,421.00			Not including estimate for 2 portable freezers or costs of items already purchased
Page 3	Analyzer, Kits for blood hormones	0.00			See Anspaugh/Hendrickson test kits estimate
Page 4	Cytology Equipment	1,312.00			Not including est for 4-head microscope
Page 5	Reagents for cytology & immunocytochemistry	933.00			
Page 6	Same as above	502.00			
Next 9 months					
Page 7	Ultrasound 140A	196,983.00			Not including the "unknown amount" of LLNL discount
Page 8	Ultrasonic dia & blood sam	10,510.00			Not including TSH kits--see Anspaugh/Hendrickson list
Page 9	Analyzer, kits for blood hormones	0.00			See Anspaugh/Hendrickson test kits estimate
Subtotal			294,971.00		

Cost estimates for equipment and supplies for the thyroid protocols for the next 12 months

Pathology Laboratory					
12 months					
Page 10	Measurement Equipment	13,569.00			
Page 11	Supplies, chemicals	6,034.00			
Page 12	Chemicals	20,046.00			
Page 13	Supplies, chemicals	16,860.00			
Page 14	Equipment, supplies	1,979.00			
Page 15	Equipment, supplies	62,734.00			Includes costs for Photomicroscope with computer system ($55 K)
Page 16	Slide stainer, slide project computer, notebook, scanners, printer	11,578.00			
Page 17	Copier, books	4,300.00			Not including costs for items already purchased
Page 18	Film, photopaper	1,500.00			
Page 19	Kodak developer, photo paper, fix agent	unk			
	Computer upgrade, modem, printer	1,750.00			Already purchased.
Subtotal			140,350.00		
Dosimetry and Risk Analysis / Ukraine Radiation Protection Institute					
	Computers, software	41,000.00			
	Fax, air conditioner,	2,410.00			
	Chairs, office supplies	700.00			Guess estimate.
Subtotal			44,110.00		
Total All Groups				732,441.00	

Dose Reconstruction Program

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September 8, 1996

TO: Addressees on previous page

TELE NO:

FAX NO:

FROM: Lynn Anspaugh

TELE NO: (510) 424-6409

SUBJECT: Meeting on September 10

MESSAGE: Neither Sheilah nor I will be attending the meeting on September 10. The Director of the NCI and the DOE Deputy Assistant Secretary for Health cut a deal in late July or early August that, as far as I understand it, gives all authority for and all *responsibility* for the two thyroid and the one leukemia project to NCI. We asked for a meeting with DOE, NCI and us for the purpose of clarifying our future role, if any, in these projects. This meeting is scheduled for September 12 and was established before your September 10 meeting was scheduled. I have made the decision not to devote effort to these projects unless and until our role is mutually negotiated and understood by all.

Based upon conversations with DOE, I believe that DOE intends that NCI assume all responsibility for the procurement of supplies and equipment. This, I hasten to add, is my own interpretation and should not be construed as an official policy statement.

In order to help with your meeting, the following is the status of the equipment and supplies for Ukraine:

> The ultrasound equipment approved by Dr. Wachholz on May 13 was shipped in late August. It should have arrived on September 9.

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A requisition for computer equipment for the dosimetry/risk analysis group that was approved by Dr. Wachholz on May 13 is in the LLNL procurement department. The order should be placed during the week of September 9.

The equipment for the DCC was approved in principle by Dr. Wachholz on May 13, but we did not receive a detailed list of equipment and software. Upon our visit to Ukraine it was apparent that the people placed in charge of the DCC had very little experience and were not prepared to specify the equipment or software. Prof. Tronko asked urgently for the participation of Herman Mitchell to make such determinations. We believe that Mitchell has not yet gone to Ukraine, but will do soon within a week or so.

A list of "critically needed" reagents and other supplies for Dr. Bogdanova was approved by Dr. Wachholz on May 13, but there has been much confusion about this list and the requests from Dr. Bogdanova. We were not familiar with many of the chemicals, but we did get cost estimates for these materials. The costs are high; these lists and the cost estimates have been provided to you previously. On August 15 Dr. Masnyk indicated that requests from Dr. Bogdanova should be tabled until "...after all the EC equipment has arrived or failed to." While this comment was made specifically concerning equipment, we note that the "critically needed" reagents are also on the EC list. Thus, we have not ordered any of the chemicals or equipment requested by Dr. Bogdanova. We hope that these materials and needs will be a major item of your discussions on September 10; as we are not clinicians or pathologists, we have nothing to add to this discussion.

While we were in Kiev in July Sheilah visited the Ford Dealer and made arrangements (with the participation of Dr. Tereshchenko and others) to buy a van for the transport of material and personnel for field screening. Although this purchase was not specifically approved by Dr. Wachholz, Dr. Masnyk did approve it before payment was authorized. This van should be delivered in early to mid November.

Some ultrasound supplies and pathology reference books (the latter at the request of Dr. Bogdanova during our trip to Kiev) were purchased and shipped and have been received. Dr. Masnyk has specifically objected to the reference texts as not having been approved by NCI. It is true that NCI approval was neither asked for nor received. We felt that we had such discretion and could not imagine that there would be objection to reference texts on thyroid pathology for an epidemiologic study of thyroid pathology. However, the money for these texts will be returned to the account for this project; I will transfer money from another account, and then make up for it by working on that project while charging my time to vacation. I will advise Dr. Bogdanova that the books are my personal gift to her.

We had agreed during our trip in July to purchase several copiers and faxes for the project, and we had placed such an order with a firm in Kiev. This purchase was not approved, although we felt it was clearly within our prerogative to order materials of such obvious need. The order has been canceled.

While in Kiev Sheilah made arrangements for e-mail. Prof. Tronko indicated that he wanted this connection to be via Dr. Bogdanova's computer. This required an upgrade to her computer, and we also purchased a printer and supplies. Although this was not specifically approved, we had strong messages from several people, including Dr. Bouville who was with us on the trip, that there was an urgent need for e-mail for Prof. Tronko's Institute. Thus, we have no regrets, but we can cancel the e-mail and take the upgrades out of Dr. Bogdanova's computer, if that is what NCI wants.

To be best of my knowledge nothing else has been ordered by us or approved by NCI, although we may be holding some minor materials for shipment. Sheilah may have some corrections to add later.

I have not calculated costs for the suggested options for the clinical chemistry tests. The costs that I sent you before, and which I am resending now, relate to what is specified in the protocols, and I have included data on the per unit costs. You can easily generate the costs of your own favorite scenario.

It may also be useful to remind you that there is roughly a two million dollar shortfall between the requirements (as mandated by the protocols) and the requests and the currently available budget for equipment and supplies for the two thyroid projects.

Have a good meeting.

Dose Reconstruction Program

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Sheilah M. Hendrickson, Executive Director
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hendrickson3@llnl.gov

September 18, 1996

Dr. Faye Austin
National Cancer Institute
Executive Plaza North, Suite 500
6130 Executive Blvd.
Bethesda, MD 20892-7362

Dear Dr. Austin:

Thank you for meeting with us on September 12. I regret the events that have led to our current situation, but I want to reiterate our desire to disassociate ourselves from the managers of your Radiation Effects Branch (REB). We desire to do this as completely as possible and as soon as possible.

As we mentioned before, we will not and cannot continue to be responsible for the purchase, delivery, and inventory of equipment and supplies for NCI/REB-related activities in the absence of our scientific involvement and our ability to verify the location and use of such equipment and supplies. We have already completed the purchases for which we had clear approval from NCI/REB. Unfortunately, we still have some deliveries outstanding and several unpaid accounts; it will also take some time to ensure the proper receipt and accountability of the equipment that has been ordered and/or sent.

The situation with the scientific activities is more complicated, as we have unfinished papers, unfinished projects, and unfinished commitments with persons and organizations. We will be working with DOE and others to wrap up any such commitments during the course of the upcoming twelve months, and it is our desire not to undertake any future commitments connected with NCI/REB-related activities. We do, of course, and as discussed during our recent meeting, intend to pursue other activities with our friends and colleagues in Belarus, Ukraine, and Russia that are not related to the activities of your Radiation Effects Branch.

One of the main purposes of this letter is to address an issue that we left on your table during the course of our meeting. This is the contract with the Russian dosimetrists, and whether the contract should be placed by LLNL, DOE, or NCI. Our basic position has been that it does not make sense for LLNL to continue with this contract in the absence of future scientific involvement in the project. Although Dr. Masnyk indicated that NCI knew nothing about this contract, the fact is that we have been working with Dr. Bouville of your staff since January in order to define the scope, milestones, and deliverables for this contract. Both Dr. Bouville and I feel strongly that the Moscow dosimetrists are essential for the success of the Belarus–US Thyroid Project, and that it is critical for the Moscow dosimetrists to be enjoined in the process now. On September 13 Ms. Hendrickson and I discussed this issue with Mr. Frank Hawkins of DOE. He was quite emphatic that DOE would not place this contract, but stated that he would be willing for us to place this contract.

I presume the issue is really one of timing, which we consider to be critical. If we hear from you by September 20, we believe that we could have this contract in operation by November 1, 1996. If you take the material that we have developed, and of which Dr. Bouville has copies, perhaps you could place the contract as quickly. If we don't hear from you by September 27, we will presume that you do not wish us to proceed in this matter.

If LLNL does place the contract, I hope it is understood completely that this will be an LLNL contract, and we will be fully responsible for its administration and the acceptance of deliverables. This would be counter to our desire for rapid disassociation, but we are willing to make an exception due to our concerns for the Moscow dosimetrists.

We hope that you will discuss this issue with Dr. Bouville.

Sincerely yours,

Lynn R. Anspaugh, Ph.D.

cc: André Bouville
Elaine Gallin

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Ms. Sheilah M. Hendrickson, Executive Director
Dose Reconstruction Program
Lawrence Livermore National Laboratory
P.O. Box 808, Mail Stop L-453
Livermore, CA 94551-9900

11 October 1996

Dear Sheilah:

In his 18 September 96 letter to Dr. Austin, Dr. Anspaugh stated that he wanted to "reiterate our desire to disassociate ourselves from the managers of your Radiation Effects Branch (REB)." Later in the same letter he said that you "still have some deliveries outstanding and several unpaid accounts." It is primarily to the second sentence that I would like to address myself here.

Indeed, I realize that one cannot cut off all ties in a given moment without concluding the actions already set in motion. To be able to deal effectively with the requests from Belarus and Ukraine, I need to have a statement from you on the status of various procurements and shipments to which you have already committed yourself. In one of your communications of last summer you showed items "on hold" and others "will order." Could you let me know what has been already sent and which of the items have been dropped from further processing by your staff? I am particularly interested in the status of the supplies for the Belarus project which were requested through you last summer and which, we were told by the Bealrusans, were to be delivered by the 15 of October, prior to initiation of the actual screening. I will certainly appreciate your kind assistance in this matter.

Best personal regards,

Sincerely yours

Ihor J. Masnyk, PhD
U.S. Project Director

Printed By: Dori Bailey 11/11/96 8:33 AM **Page:** 1
From: Sheilah Hendrickson (11/5/6) Robert Glouvtchinskii (11/5/96)
To: Robert Glouvtchinskii
CC:
BCC:
Priority: Normal **Date sent:** 11/5/96 12:11 PM

Reply to: RE>Copy-Fax machine

Hello Robert!!!! How are you? It was very nice to receive you message. Unfortunately, I am monitoring my e-mail from home. I was unexpectedly in the hospital beginning October 25. I am now home and will return to work on November 8. I will review my files and be in contact with you shortly after my return.
Please send my best regards to Lyna, Ilya and Sergey. We missed you and Lyna and Sergey after you all left! I am sure your family was very happy to see you. I will contact you soon.
Sheilah

Date: 11/5/96 5:49 AM
To: Sheilah Hendrickson
From: Robert Glouvtchinskii
Hi Shielah! How are you!

Lina pass halo and asks about copy-fax machine.
We have received some stuff from ComputerLand
but this machine not present in his list.

She want obtain some information about it.

Good bye and sorry for my English.
Pass my best wishes to everyone.

Robert

----------------- RFC822 Header Follows -----------------

```
Received: by quickmail.llnl.gov with ADMIN;5 Nov 1996 05:47:17 -0800
Received: from creator.gu.kiev.ua (root@creator.gu.kiev.ua [194.93.190.3]) by
whale.gu.kiev.ua (8.7.5/8.7.3) with ESMTP id PAA23686 for
<Sheilah.Hendrickson@quickmail.llnl.gov>; Tue, 5 Nov 1996 15:47:14 +0200
Received: from rpi.UUCP (uurpi@localhost) by creator.gu.kiev.ua  with UUCP id
PAA17469 for Sheilah.Hendrickson@quickmail.llnl.gov; Tue, 5 Nov 1996 15:45:13
```

- more -

Dose Reconstruction Program
(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

November 8, 1996

Ihor Masnyk
National Cancer Institute
Building EPN, Room 530
Bethesda, Maryland 20892

Dear Ihor:

Due to an unexpected hospitalization a couple weeks ago, I am only now (my first day back at work) able to reply to your letter.

Answers to your questions and statements can be found in several faxes/letters previously sent from LLNL to you, others at NCI, and other American team members. I refer you to correspondence dated August 9, August 13, and September 8, 1996, among others. In addition you may want to contact DOE, funding sponsor for equipment and supplies, for copies of the following official FY 96 reports: (1) FY 96 Financial Closing, DOE Capital Equipment—Belarus / Ukraine, October 18, 1996, and (2) DOE/NRC, Semi/Annual Report, October 1995 through September 1996, October 16, 1996, Belarus / Ukraine.

I remind you that last August LLNL sent to you, others at NCI, and other American team members, equipment and supply requests with date needed from both Belarus and Ukraine. Upon NCI receiving this information from LLNL, NCI has not provided to LLNL Belarus project directions and no approved listings for purchase and delivery of equipment and supplies to Belarus. NCI has stated several times in the last several months that equipment and supplies must be thoroughly reviewed and approved by NCI, after all, we (NCI) will have to make the ultimate decision of what to approve for procurement.

LLNL has performed their responsibilities in organizing the equipment and supply requests and sending it forward to NCI. This is a most unfortunate situation. Belarus is ready to start work and expecting delivery of supplies, but NCI did not provide LLNL with project directions nor any approvals to procure equipment and supplies for Belarus.

Sincerely,

Sheilah Hendrickson

Sheilah Hendrickson

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program
Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-286, Livermore, CA 94551-9900
University of California
Fax (510) 424-6408
Telex (910) 386-8339

Dose Reconstruction Program

(Former Risk Sciences Center)

Lynn R. Anspaugh, Scientific Director
(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

November 11, 1996

TO: Dr. Ilya Likhtarev
011-380-44-213-71-92

Dr. Nikolai Tronko
011-380-44-430-36-94

Dr. Elaine Gallin
Mr. Barry Fountos
8-1-301-903-1413

Dr. Shlomo Yaniv
8-1-301-415-~~6239~~ 5385

Dr. Ihor Masnyk
8-1-301-496-1224

FROM: Sheilah Hendrickson TELE NO: (510) 424-6410

We are transmitting 3 pages (including this cover sheet).

Health and Ecological Assessment Division
Atmospheric and Ecological Sciences Program
Environmental Programs Directorate
Lawrence Livermore National Laboratory, P.O. Box 808, Mail Stop L-286 Livermore, CA 94551-9900
University of California
Fax (510) 424-6408
Telex (910) 386-8339

Dose Reconstruction Program
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(510) 424-6409
anspaugh1@llnl.gov

Sheilah M. Hendrickson, Executive Director
(510) 424-6410
hendrickson3@llnl.gov

November 11, 1996

Dr. Ilya Likhtarev
Director
Ukraine Radiation Protection Institute
53 Meinkova Street
Kiev, Ukraine 252050

Dear Ilya:

Due to an unexpected hospitalization and illness a couple weeks ago, I am only now able to reply to your e-mail via Lyna and Robert. They stated that some equipment from ComputerLand was received, but inquired about the copy-fax machine.

During the July 1996 LLNL/NCI team (Anspaugh, Bouville, Hendrickson) visit to Kiev, we discussed and agreed in separate meetings with you and Dr. Tronko to purchase several copiers, faxes, cooler/heater systems, telephones, and paper for the project. The LLNL/NCI team felt it was important and necessary to improve the communication capabilities at both the IEM and URPI and to prepare for the establishment of the DCC and project office. Returning to LLNL, my staff prepared an order to purchase the above items.

However, on August 15, 1996, I received a letter from NCI, Ihor Masnyk, reminding me there was only a limited number of items (lists from Ukraine) approved for purchase by NCI during a May meeting of the U.S. team members. He further stated that was the extent of their decision and he wanted to see that we did not exceed it without a persuasive reason and only after a thorough review by NCI staff and specific approval for all additions. He asked that we abide by the decisions made in May and stated that we (NCI) will make the ultimate decision of what to approve for procurement.

During my vacation (September 8, 1996) Dr. Anspaugh sent to NCI the status of equipment and supply orders for Ukraine. He advised NCI that although the above order (copiers, faxes, etc.) was not approved, we certainly felt it was within our prerogative to order materials of such obvious need. But because of the August 15, 1996 letter from Ihor Masnyk, we canceled the order. We did not receive any comments or requests to do otherwise from NCI regarding the items mentioned in Dr. Anspaugh's letter.

I regret any inconvenience this may have caused the project, but I thought I understood from Dr. Anspaugh that this was all explained to you during his last visit. Perhaps you and Dr. Tronko may want to communicate with Ihor Masnyk regarding the need for the above items that were not approved by NCI for purchase. I might also mention that on August 7, 1996, Ihor Masnyk, did congratulate me on the speedy action for the mini-bus (van) and approved it for purchase.

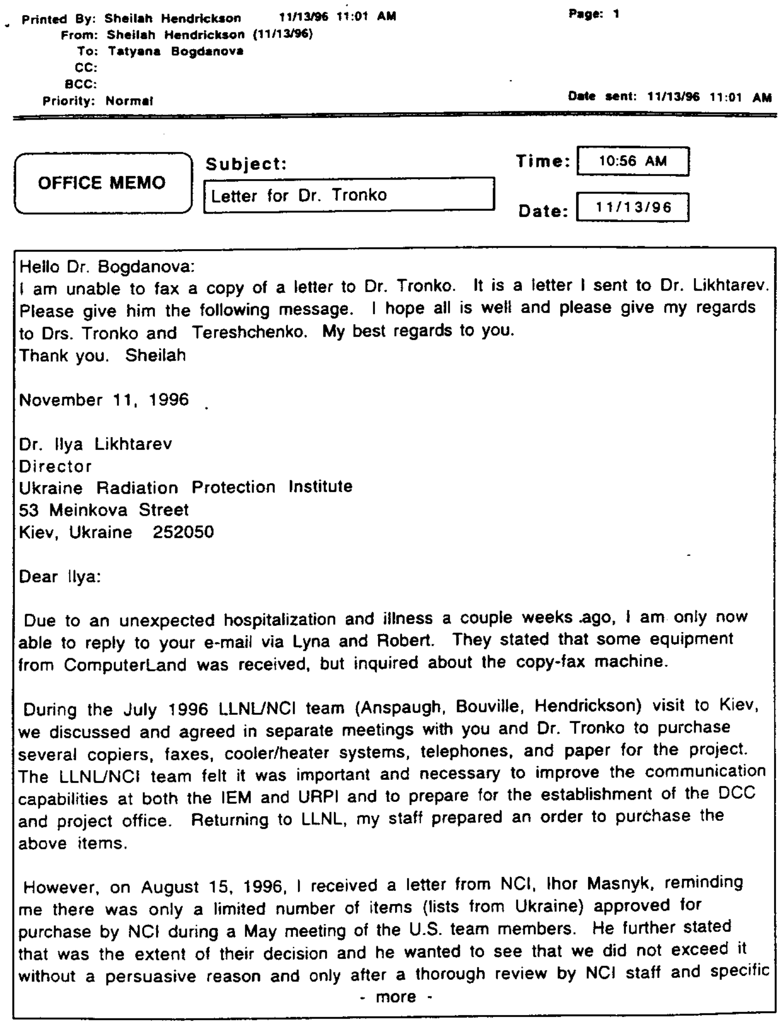
Sincerely,

Sheilah Hendrickson

Sheilah Hendrickson

Copies:

Dr. Nikolai Tronko
Dr. Lynn Anspaugh
Dr. Elaine Gallin
Mr. Barry Fountos
Dr. Shlomo Yaniv
Dr. Ihor Masnyk



Printed By: Sheilah Hendrickson 11/13/96 11:01 AM
From: Sheilah Hendrickson (11/13/96)
To: Tatyana Bogdanova
CC:
BCC:
Priority: Normal

Page: 1

Date sent: 11/13/96 11:01 AM

OFFICE MEMO

Subject: Letter for Dr. Tronko

Time: 10:56 AM

Date: 11/13/96

Hello Dr. Bogdanova:
I am unable to fax a copy of a letter to Dr. Tronko. It is a letter I sent to Dr. Likhtarev. Please give him the following message. I hope all is well and please give my regards to Drs. Tronko and Tereshchenko. My best regards to you.
Thank you. Sheilah

November 11, 1996

Dr. Ilya Likhtarev
Director
Ukraine Radiation Protection Institute
53 Meinkova Street
Kiev, Ukraine 252050

Dear Ilya:

Due to an unexpected hospitalization and illness a couple weeks ago, I am only now able to reply to your e-mail via Lyna and Robert. They stated that some equipment from ComputerLand was received, but inquired about the copy-fax machine.

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- more -

From: Sheilah Hendrickson (11/13/96)
To: Tatyana Bogdanova
CC:
BCC:
Priority: Normal **Date sent:** 11/13/96 11:01 AM

---

approval for all additions. He asked that we abide by the decisions made in May and stated that we (NCI) will make the ultimate decision of what to approve for procurement.

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Sincerely,

Sheilah Hendrickson

Copies:

Dr. Nikolai Tronko
Dr. Lynn Anspaugh
Dr. Elaine Gallin
Mr. Barry Fountos
Dr. Shlomo Yaniv
Dr. Ihor Masnyk

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

January 2, 1997

Mr. James Taylor
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Taylor:

The Nuclear Regulatory Commission (NRC) for many years has been constant in its support for the Chernobyl-related studies of thyroid disease, especially cancer, among children in Ukraine and in Belarus, and of leukemia among cleanup workers in Ukraine. More recently, this support has been most tangible in the transfer of $1,000,000 to the Department of Energy (DOE) for equipment and supplies primarily for the thyroid studies and in arranging for the $250,000 contributed by the Institut de Protection et de Sûreté Nucléaire (IPSN) for similar support for the leukemia study.

As you know, negotiations between the National Cancer Institute (NCI) and the DOE have led to a recent Interagency Agreement (a copy of which you have received) that assigns to the NCI responsibility for all aspects of these studies, including the procurement and shipment of equipment and supplies. Initial equipment and supplies have already been purchased and delivered, particularly for Belarus. However, in reviewing (1) the current projected equipment and supply needs for the immediate future (i.e., through the expected 18-month duration of Phase 1 of the leukemia study, and through the end of calendar year 1998 for the thyroid studies), and (2) the funds estimated to be available for this purpose (i.e., $250,000 of support from the IPSN plus the unspent balance of monies transferred to the DOE by the NRC), it is apparent that current available equipment and supply funds are not adequate to provide for projected needs:

	Thyroid Belarus Study	Thyroid Ukraine Study	Leukemia Study	Total
Projected needs	$225,000	$655,000	$452,000	$1,332,000
Estimated funds available	$180,000*	$450,000*	$250,000	$ 880,000*
Additional funds needed	$ 45,000	$205,000	$202,000	$ 452,000

*Based upon unofficial conversations.

It is apparent that there exists an estimated current shortfall approaching $500,000. Included in this estimate is the increase in the quantity of supplies that will be required for these studies as the number of subjects increases, in some areas dramatically so, during the next several years. This will require a proportionate increase in the cost of supplies. For example, accrual of thyroid subjects in Belarus is projected to increase from 3,000 in the first year to 15,000 in the third year; comparable numbers in Ukraine are projected to be 15,000 and 50,000, respectively.

A large number of the study subjects in Belarus, perhaps even a majority, reside in locations more distant from Minsk than was originally expected. It is apparent that this accrual of thyroid subjects will require that examination facilities be established also in one or more oblasts beyond Minsk (especially Gomel and possibly Brest) and that additional mobile teams of physicians will need to be equipped to examine subjects in the remote rural regions. The equipment costs for these additional stationary and mobile examination centers are not included in the above figures and will add to the estimated shortfall. Maintenance contracts and future equipment replacements also need to be factored into future cost estimates. Therefore, our current projected estimate for equipment and supply needs for the three projects for the next two years, including the shortfall indicated above, is of the order of $1,000,000

For the above several reasons, it would be very much appreciated if the NRC again would consider additional support for equipment and supplies. While any level of support would be welcome, might it be possible for the NRC to consider as much as $1,000,000 for the next two-year period? This surely would be most helpful. Even though the NCI and the DOE will fund these projects at a level of approximately $1.5M per year, it is expected that these monies will be needed to cover the operational costs: a support contractor, expanded professional personnel needs, increased government and non-government travel, support for the binational advisory groups, training, meetings, etc. These NCI and DOE funds are not expected to provide for equipment and supply needs, nor do they cover NCI professional and support staff time, which the NCI additionally contributes to these projects. NRC assistance to the NCI for continued support of these projects, therefore, specifically for equipment and supplies, is expected to be critical to their success.

Thank you for consideration of this matter at your earliest opportunity. Please contact me if you have any questions or if additional clarification would be helpful.

Sincerely,

Bruce W Wachholz

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

ATTACHMENT

30

MEMORANDUM OF AGREEMENT
FY 1998
BETWEEN
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL CANCER INSTITUTE
AND
THE DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH

This memorandum sets forth the terms of agreement in FY 1998 between the Department of Health and Human Services (HHS), National Cancer Institute (NCI), and the Department of Energy (DOE), Office of Environment, Safety and Health for joint implementation of the project, "U.S./Belarus/Ukraine Joint Research on the Biomedical Effects of the Chernobyl Reactor Accident."

I. DESCRIPTION OF SERVICES

This agreement is a mechanism to implement the transfer of funds to provide partial support for the Chernobyl-related leukemia and thyroid disease epidemiology studies in Ukraine and the thyroid disease epidemiology study in Belarus in fiscal year (FY) 1998 from DOE to HHS, NCI, and to define the responsibilities of each Agency with respect to these studies.

These studies will operate under the auspices of the Joint Coordinating Committee for Civilian Nuclear Reactor Safety (JCCCNRS) and applicable Binational Agreements. The total cost of these projects in FY 1998 estimated by NCI is around $2.5 million, exclusive of the cost of equipment and supplies and contributions from other agencies and/or countries.

A. DOE makes a commitment to:

Transfer at the proper time in FY 1998 agreed-upon funds to NCI to cover administrative, logistical, managerial, equipment, and supply costs incurred in the execution of activities directly related to the leukemia and thyroid disease epidemiology studies in Ukraine and the thyroid disease epidemiology study in Belarus. DOE will contribute up to $800,000 from the FY 1998 budget.

B. NCI makes a commitment to:

1. Assume all responsibility for management, coordination and oversight of the design, implementation, analysis and scientific interpretation of the results of leukemia and thyroid disease epidemiology studies of Chernobyl-exposed populations in Ukraine and Belarus.

2. Manage, coordinate and oversee the projects using staff of the NCI and/or of an NCI funded scientific and technical support contractor.

3. Assume responsibility for all official policy, financial, management and scientific matters with the governments of Belarus and Ukraine and their relevant organizational entities and personnel.

4. Act as the sole contact point for all official project-related communications between U. S. agencies and their contractor personnel and Ukraine and Belarus Ministries and collaborating institutions and individuals. This is not intended to preclude personal scientific or technical discourse among or between scientists and physicians or limit unofficial interactions between interested parties.

5. Develop milestones on a quarterly basis for the ongoing program to be used in evaluation of the progress of the project and for authorization of payments for local support.

6. Share all reports regarding these projects with DOE and, when appropriate, with other relevant U. S. Government Agencies (Nuclear Regulatory Commission and Department of State).

7. Provide DOE with annual progress and financial reports.

8. Invite DOE observers to all review and reporting sessions.

9. Contribute financial resources from its FY 1998 budget of at least matching funds toward the implementation of the projects. (If DOE support and NCI matching funds are not sufficient to fully implement the protocols, and the remaining shortfall cannot be met from other sources, the scope of the project(s) will be revised.)

II. DURATION OF AGREEMENT

This agreement is effective when signed by both parties and shall remain in effect through the end of FY 1998 unless amended by mutual written consent of both parties. The agreement is to be renewed annually thereafter by written mutual agreement and will correspond to the Federal fiscal year. There is every intention to continue this agreement to ensure satisfactory completion of these projects.

III. PAYMENTS TO BE MADE TO: NATIONAL CANCER INSTITUTE

Reimbursement by Standard Form 1080 or 1081 or Treasury Online Payment and Costing (OPAC) system.

Submit billing to:

FINANCE DIVISION
P.O. BOX 2001
OAK RIDGE, TN 37831

IV. REIMBURSING AGENCY CODE: DE-A105-92EH89188.000

This agreement will operate under the following NCI codes:

Agreement Number:	Y3-CB-0020
Appropriation:	7570849
Common Account Number:	7-8422517

V. LEGAL AUTHORITY

The legal authority for NCI to enter into this agreement is encompassed within the provisions of the Economy Act of 1932 as amended (31 U.S.C. 1535 and 1536).

VI. TRAVEL

Travel under this agreement is subject to allowances authorized in accordance with the Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Services Regulations.

VII. EQUIPMENT

Any equipment procured shall not be required to be returned to DOE or NCI.

VIII. PROJECT OFFICERS

NCI: IHOR J. MASNYK, Ph.D.
Radiation Effects Branch
National Cancer Institute
EPN, Suite 530
Bethesda, MD 20892-7391
Tel: (301) 496-9326
Fax: (301) 496-1224
e-mail: masnyki@epndce.nih.gov

DOE: BARRETT N. FOUNTOS
U.S. Department of Energy
Office of International Health Programs
EH-63/270CC
19901 Germantown Road
Germantown, MD 20874-1290
Tel: (301) 903-6740
Fax: (301) 903-1413
e-mail: barrett.fountos@eh.doe.gov

IX. MODIFICATIONS OR CANCELLATIONS

This agreement, or any part of its specific provisions, may be revised by signature approval of both parties signatory hereto. Cancellation of the agreement may be accomplished only at the expiration of 90-day advanced notification by either party.

X. RIGHTS IN DATA

NCI may:

1. Establish a claim to copyright scientific or technical articles based on, or containing, data first produced in the performance of this agreement.

2. Use, release to others, reproduce, or publish any data first produced in the performance of this agreement, provided that a copy of the final document is provided to DOE.

STATEMENT OF WORK SUMMARY

DOE will provide a portion of the funds required (up to $800,000) for the performance of specified activities in support of the three projects (U.S.-Belarus Thyroid, U.S.-Ukraine Thyroid, U.S. - Ukraine Leukemia) in FY 1998. NCI will contribute at least matching funds to carry out these three projects.

In addition, NCI (Radiation Effects Branch), in consultation with Binational Advisory Groups and working groups of experts, tailored to specific technical requirements, will assume full responsibility for design, implementation, analysis and scientific interpretation of leukemia and thyroid disease epidemiologic studies of Chernobyl-exposed populations in Belarus and Ukraine; manage, coordinate and oversee all ongoing activities; assume responsibility for all official policy, management issues, and all financial matters; be the sole source of all official contacts for project-related communications between all participating entities: U.S. Agencies, contractors, advisors, consultants, and Belarus and Ukrainian organizations and personnel. This is not intended to preclude personal scientific or technical discourse among or between scientists and physicians or limit unofficial interactions between interested parties.

NCI will provide DOE copies of all reports, minutes of meetings, and other documentation related to these studies and will provide DOE an annual progress/financial report within 30 days of the end of the fiscal year. NCI will invite DOE staff as observers to program reporting sessions.

NATIONAL CANCER INSTITUTE	DEPARTMENT OF ENERGY
Richard D. Klausner, M.D. Director National Cancer Institute National Institutes of Health	Peter N. Brush Acting Assistant Secretary for Environment, Safety and Health Department of Energy
Date:________________	Date: May 5 1998

ATTACHMENT

31

INTERAGENCY AGREEMENT
BETWEEN
NATIONAL CANCER INSTITUTE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
VETERANS AFFAIRS NATIONAL ACQUISITION CENTER
DEPARTMENT OF VETERANS AFFAIRS
Fiscal Year 1997
Bethesda, MD 20892

This memorandum sets forth the terms of agreement between the National Cancer Institute (NCI), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), and the Veterans Affairs National Acquisition center (VANAC), Department of Veterans Affairs (VA), entitled **"Provisions of Equipment and Supplies for Epidemiologic Studies of Radiation-Induced Thyroid Disease in Belarus and Ukraine".**

I. DESCRIPTION OF SERVICES:

This agreement is a mechanism to implement the transfer of funds from the NCI to the VANAC for procurement and delivery of equipment and supplies to be specified by the NCI, including the provision of necessary equipment service contracts, to participating organizations in Belarus and Ukraine. The Department of Energy (DOE) and the Nuclear Regulatory commission (NRC) are participating with the NCI in funding epidemiological studies of radiation-induced thyroid disease in Belarus and Ukraine conducted under the auspices of the Joint Coordinating Committee for Civilian Nuclear Reactor Safety (JCCCNRS) Working Group 7 (WG 7) or similar letter arrangements for continuing cooperation. The NCI is responsible for the management and coordination of these long-term projects (anticipated to last at least 10 years), the overall design of the study, its implementation, and the analysis and scientific interpretation of the data obtained. The funds for this activity originate both at the NCI and at other U.S. Government agencies that transfer money to NCI. The initial transfer of funds for the thyroid cancer study from the NCI to VANAC during Fiscal Year (FY) 1997 will be $584,300 of which $181,900 is designated for the study in Belarus and $402,400 is for the study in Ukraine.

II. PERIOD OF PERFORMANCE:

The period of performance extends from the acceptance of this agreement by both parties through September 30, 1997, with an annual renewal option to be implemented 90 days prior to the expiration of the agreement.

Original

III. SCOPE OF WORK:

Equipment and supplies shall be purchased and shipped as specified and directed by the NCI Project Manager to specific persons and locations in Belarus and Ukraine. The equipment and supplies purchased will be used to support work performed as stated in the "Scientific Protocols for Epidemiologic Studies of Radiation-Induced Thyroid Disease in Belarus and Ukraine".

IV. REPORTING REQUIREMENTS:

QUARTERLY FINANCIAL LETTER REPORTS:

Each quarter, VANAC will submit a brief status report which summarizes the expenditure of NCI funds. This report shall provide an itemized listing of the equipment and supplies purchased within the quarter, all costs (including Contractor Costs, see Section VII, infra, as necessary) associated with the purchase (including information required by the NCI property management system such as serial number on accountable equipment), and information on shipping costs and recipients of items. In addition, each report shall include a.) costs of the previous quarter, b.) cumulative costs and uncosted obligations to date, and c) projection by quarter for the remainder of NCI obligated funds. The first quarterly report shall provide the initial projections, and subsequent reports shall either indicate revised projections or indicate "no change in the cost and uncosted expenditure projection". These reports will be transmitted by NCI to other agencies with financial interests in the project.

TECHNICAL LETTER REPORTS:

VANAC shall prepare quarterly technical reports which summarize any additional significant findings, difficulties encountered, suggestions or comments which might be beyond the scope of information provided in the quarterly financial letters.

Both reports shall be submitted by the 10th of the month (in April, July, October and January) following the end of each quarterly reporting period. Reports shall be addressed to:

Project Manager, Chernobyl Studies
Radiation Effects Branch
6130 Executive Blvd.
EPN Room 530, MSC 7391
Rockville, MD 20852-7391

V. EQUIPMENT:

It is the intent of the NCI that title for all accountable equipment shall vest with the NCI, and that NCI personnel will enter information provided by VANAC into the NIH property management system, and that such equipment shall be permanently donated to the receiving parties using procedures specified by the NIH.

VI. ESTIMATE OF COST AND OBLIGATION OF FUNDS:

Funds for this initial agreement are being provided to NCI by NRC to assist in purchase of equipment, supplies and logistics only. Initial FY 97 funding for this study is $584,300 and this amount is hereby obligated.

VII. FUNDS AVAILABILITY

Advance payment to VANAC of any NCI funds obligated to this agreement is authorized by NCI. Any NCI funds remaining unexpended at the end of a fiscal year must be deobligated and returned to the NCI by September 20th for budget close-out. Upon renewal or modification of the agreement between NCI and VANAC, funds would be available on the same basis through a modification of this agreement.

The NCI agrees to reimburse VANAC for costs associated with the negotiation, award, and administration of any solicitation, contract or delivery order issued pursuant to this agreement (Contractor Costs) at a rate of 6% of the contract price. Estimated Contractor Costs for FY 1997 are $35,058.

Reimbursement of Contractor Costs shall be made annually by depositing funds to an account designated by VANAC. Initially, payment shall be made when this agreement is executed. If additional funds are made available in future years, payment shall be made during the first month of the first quarter of each fiscal year that this agreement is in effect, or as soon as funds become available to the NCI. Funds on deposit shall be reviewed at the beginning of each calendar quarter and adjustments, if any, will be made by agreement between VANAC and NCI.

VIII: BILLING INSTRUCTIONS:

To receive payment under this agreement, VANAC should bill through the OPAC system to the following address and state on the OPAC billing that this is an Advance Payment.

National Institutes of Health
Government Accounting Branch
31 Center Drive
31/B1B05A
Bethesda, MD 20892

IX. ORDERING:

All orders will be submitted to:

Philip D. Naas
Management Analyst (90N-M)
VA National Acquisition Center
PO Box 76
Hines, IL. 60141
Telephone: (708) 786-5144
FAX:(708) 786-5147

The following persons are authorized by NCI to place orders with VANAC:

Dr. Ihor J. Masnyk

Dr. Bruce W. Wachholz

X. DELIVERY:

Deliveries will be made utilizing the most economical mode of transportation necessary to meet delivery deadlines. Delivery points are:

Belarus: Minsk and Gomel

Ukraine: Kiev

Russian Federation: Moscow

Delivery charges not covered by contract source will be added, as a separate line item, to each individual invoice and will be covered by NCI. Any Customs and/or Duty requirements will be the responsibility of NCI. All shipments will be made directly to delivery points specified by NCI.

XI. RISK OF LOSS

Risk of loss or damage to the equipment or supplies provided under this Agreement shall remain with the supplier of such equipment or supplies until, and shall pass to NCI upon:

(1) Delivery of the equipment or supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the equipment or supplies at the destination specified by NCI, if transportation is f.o.b. destination.

XII. ACCEPTANCE:

NCI will confirm acceptance of all deliveries within 7 work days. Discrepancies in shipments shall be reported immediately to the contractor and to the VANAC.

In the event that a site visit is required by VANAC, expenses shall be covered by NCI.

XIII. CONTACTS:

NCI Project Manager:
Dr. Ihor Masnyk
Radiation Effects Branch
National Cancer Institute
6130 Executive Blvd, Suite 530, MSC 7391
Rockville, MD 20852-7391
Telephone: (301) 496-9326
Fax: (301) 496-1224
Email: im13q@NIH.gov

NCI Administrative Contact:
Ms. Joy Osborne
Administrative Officer, DCB
National Cancer Institute
6130 Executive Blvd., Suite 500, MSC 7380
Rockville, MD 20852-7380
Telephone: (301) 496-2871
Fax: (310) 496-8656
Email: jo25x@nih.gov

VANAC Administrative Contact:
Philip D. Naas
Management Analyst (90N-M)
VA National Acquisition Center
PO Box 76
Hines, IL 60141
Telephone: (708) 786-5144
Fax: (708) 786-5147

VANAC Contracting Contacts:
Medical Equipment, Reagents, & Other Equipment
Jessie Holder, Chief
Medical Equipment (90N-M3)
VA National Acquisition Center
PO Box 76
Hines, IL 60141
Telephone: (708) 786-5250
Fax: (708) 786-5256

Medical Supplies:

Burnell Brusveen
Contract Specialist
Medical Supplies (90N-M1)
VA National Acquisition Center
PO Box 76
Hines, IL 60141
Telephone: (708) 786-5139
Fax: (708) 786-4974

XIV. TERMINATION OF AGREEMENT:

This agreement may be terminated by either party upon 90 days written notice to the other party. Any project expenses up to the termination date will be paid by NCI. Any expenses incurred in terminating this agreement will be paid by the party terminating the agreement. Any unexpended funds shall be returned to NCI.

XV. AUTHORITY

This agreement is entered into under the authority of the Economy Act, sections 1535 & 1536 of Title 31, United States code, as amended (31 U.S.C. 1535). The requesting organization, NCI, has considered the requirements of FAR 17.502 and 17.503(a) and (b) and has provided determinations and findings (D&F) pursuant thereto.

XVI. DISPUTE RESOLUTION

NCI and VA agree to take immediate action to resolve issues and disagreements that arise in accomplishing work under this agreement, in accordance with FAR 17.504 (c). In the event that disagreements arise that cannot be resolved by the Signatories, then the parties will submit such disagreements to their respective legal representatives for resolution under a mutually acceptable NCI or VA alternative dispute resolution process.

This agreement is hereby accepted by both parties.

Accepted by Department of Veterans Affairs	Accepted by National Cancer Institute
Signature: Nancy L. Darr	Signature: Joy Osborne
Name: Nancy L. Darr (typed)	Name: Joy Osborne (typed)
Title: Executive Director	Title: Acting ARC Manager, DCB, NCI
Date: 5-9-97	Date: 5/8/97

Department of Health and Human Services
National Institutes of Health
Agency Agreement and Clearance

☐ Intra-agency Agreement (within NIH)
☒ Inter-agency Agreement (outside NIH)

Title of the Agreement: Provisions of Equipment and Supplies for Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus and Ukraine

Summary of Substance of the Agreement (include purpose, resources committed: funds, personnel, equipment, facilities, etc.):
This agreement transfers funds from the NCI to the Veterans Administration National Acquisition Center [VANAC] for procurement and delivery of equipment and supplies to participating organizations in Belarus and Ukraine. The epidemiological studies of radiation induced thyroid disease are conducted under the auspices of the Joint Coordinating Committee for Civilian Nuclear Reactor Safety [JCCCNRS] Working Group 7. The funding specified in this agreement is from monies originally supplied to NCI by the Nuclear Regulatory Commission [NRC] at a total of $584,300 [$181,900 is designated to Belarusian study; $402,400 is for Ukrainian study]. PAYMENTS FOR SERVICES OR EQUIPMENT SUPPLIED BY VANAC MUST BE MADE IN ADVANCE.

Delegations of Authority Under the Agreement:

This agreement is made in accordance with the authority in Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535) and 42 U.S.C. 321.

Period of the Agreement: 5-8-97 through 9-30-97

Billing Information

Paying Agency: National Cancer Institute Agency Location Code: 75080031 Address: 9000 Rockville Pike OAB, OFM Building 31, Room B1B54 Bethesda, MD 20892	Receiving Agency: VANAC Agency Location Code: 36001200 Address: PO Box 76 Hines, IL 60141

Accounting Information						
Paying Federal Agency	Agreement Number (for NIH Y1/Y2)	Appropriation	CAN	Amount	*Signatories (Name, Title)*	*Date*
NCI	Y1-CB-7005-01	7570849	7-8333469	$584,300.00	Joy Osborne, Acting ARC Manager Division of Cancer Biology/NCI/NIH	5-8-97
					Joy Osborne	

Accounting Information						
Receiving Federal Agency	Agreement Number (for NIH Y3)	Appropriation	CAN	Amount	*Signatories (Name, Title)*	*Date*
VANAC	VANAC has no agreement nos.			$584,300.00	Nancy L. Darr, Executive Director VANAC	5-9-97
					See Attachment for VANAC Signature	

NIH Project Officer, ICD, Phone	*NIH Administrative/Budget Office Contact, ICD, Phone*
Bruce Wachholz, PhD NCI/DCB/REB (301)496-9326 EPN 530	Joy Osborne, Acting ARC Mgr DCB/NCI (301) 496-2871 EPN 500

DHHS/NIH Clearances	ICD:	
	Signature:	

NIH 1742 (rev. 10/95) C:\ FILE NAME

Masnyk, Ihor

From: Beebe, Gilbert
To: Masnyk, Ihor
Subject: Mess and things
Date: Friday, August 01, 1997 9:56AM

Ihor. You probably have the equivalent of this in a separate message, but, just in case you don't. I think this is an important statement, not only with respect to the logistics of supplies and equipment but also with respect to where Everett is in relation to the project and NCI. I think it would be good for him to have the various access names and numbers for the Chicago outfit. It would also seem to me about time for you to make a visit there with him.
Gil

FORWARDED FROM: Beebe, Gilbert
Microsoft Mail v3.0 (MAPI 1.0 Transport) IPM.Microsoft Mail.Note
From: Everett K. Mincey
To: Gilbert Beebe
Beebe, Gilbert
Subject: Mess and things
Date: 1997-08-01 00:03
Priority: 3
Message ID: 4EF81A950A0AD11186400080SFEACCE5

Dear Gil:

Sorry about mess with NCI and I-31 and etc. I know about it second hand, of course, not having seen newspapers in US about reporting of such. I had email from Ihor about Vanac, but they haven't called me. I will get off a fax to them, suggesting that if they have problems, to phone me. I know that they will have some problems, consider that it took us over a year with LLNL and Sheilah to get it running smoothly. Even then, when I lived in Minsk, I received phone calls weekly at my apartment from LLNL about supplies and shipping problems- usually from Sheilah's assistant Joe. They were very good and faithful about phoning me in Minsk, even if there were no problems, just to touch base with me about supplies. I do not expect the same from VANAC. I have card from point person in VANAC but no email number. Just phone and Fax. I would have thought that they would have some questions by now! There will be many questions in the future about supplies and I do have much apprehension about the hand-holding process with VANAC. From experience with LLNL I know that there will be a learning process-over the next year. I will hold their hand is they ask. Ihor mentioned that we may have to visit them again but I think we can do it over phone-if they phone. I want to encourage them to phone and ask questions-not just go ahead with what they think is OK. There will be some special arrangements with on-going supplies as far as chemistry is concerned. I have particular concerns about how they will arrange with standing orders for chemistry supplies, etc. I do have concerns about quick shipment of necessary items for on-going supplies.

All will become clear in the future, I hope-with VANAC. They must maintain close contact with us and ask questions. I do not think that VANAC has a clear idea of how much close contact is required for our projects. As you know, LLNL attended many of our sessions in Washington and it took some time to get it all together for a smooth flow of supplies. I still have questions about the ability to procure supplies on the local economy. I have mentioned it to Ihor but have not received answer. You know that Sheilah was able to go to Minsk, for example, and buy things on the local economy. We must be able to do the same now-but the mechanism for doing that is not clear to me. For example, if we want to buy furniture, refrigerators, computer supplies, etc in Kiev-how will we do that? I have offered to Ihor to be the "purchasing arm" for VANAC for local economy items but do not know where that idea is at the moment. I do not feel that we should continue to rely on me putting items on my Visa card-surely there can be a better way to buy things on the local economy! Sheilah managed to take money and/or checks to buy items in Belarus. I could do the same, I suppose.

Since there are ambiguous questions about me going to Kiev-or anywhere for that matter-I will just have to await Ihor's return and see what transpires. If NCI recognizes that something other than quarterly visits is required I will listen. Otherwise, I will send my comments to NCI by mail-quarterly visits will not suffice to make projects work well-we all know that-

As an item left out of my previous email to you,and regarding testing from Gomel subjects, it is my thought that all urinary iodine samples, as well as other biological samples would some back to Minsk. I know that we haven't had much discussion about Gomel-and I do not think that we will resolve any Gomel issues until we have more discussions with principals in Minsk-but as a first approximation-we will consider sending samples back to Minsk-from Gomel. I believe that we will have many problems in coordination with any Gomel operation which we undertake- and nothing but a constant person in Belarus will make Gomel come on line properly. This is a delicate and sensitive issue-all around-with many overtones-which I understand-and I believe that Ihor understands them as well. Gomel is not a simple issue!!!

Regards

Everett

Have a nice holiday and relax.

Masnyk, Ihor

From: Everett K. Mincey
To: Beebe, Gilbert; Gilbert Beebe; Masnyk, Ihor
Subject: VANAC
Date: Saturday, August 02, 1997 12:43AM

Dear Gil and Ihor:

Received letter and list from VANAC-which I will fax to NCI so that you(Ihor) will have it on Monday. I sent FAX reply, copy of which is also sent to your office at NCI. Letter from VANAC does not list NCI as recipient so thought that I should send whole thing to NCI. I hope my reply was acceptable to NCI. I have some problems speaking for NCI-but in view of Ihor's letter, leaving me in charge-so to speak-of supply problems-I thought that I could address their concerns in a general way.

It is apparent that we have major problems with VANAC-which is not unexpected considering that we had just one meeting with them-before they received our list of supplies. When I consider the close relationship we(I) had with LLNL and the amount of time it took to develop that relationship-I am not surprised at the confusion at VANAC. It appears to me that the supply issue is going to be one of the major hang-ups for the projects at this point. We cannot expect any agency to just pick up the ball and run with it-there so many exceptions-so many little quirks-to our projects supply needs that no "generic" purchasing organization can cope with it fully-without an almost full-time person from NCI side to guide them constantly. Even though LLNL and Sheilah had a good understanding of our projects, I was phoned at least twice weekly when I lived in Minsk by LLNL to answer questions. Dr. W. knows that is true. I could expect their phone calls from LLNL and enjoyed them. Also when I was in Vancouver, Sheilah phoned me constantly to ask about this and that-not just laboratory things but the whole spectrum of things for Minsk. I am afraid that the level of communication with VANAC will not reach that point. What I am trying to say is that with the complexity of our supply requirements for projects in Minsk and Kiev -VANAC will have real problems in coping. It is not their fault-we just have a complexity of things on an ongoing basis and it took Sheilah and I two years of constant communication to work it all out. I am sorry to keep mentioning LLNL but I only do it to illustrate the realities of the situation.

There are many realities which impinge on our project-now that LLNL has left. One which I keep mentioning is the ability of local purchasing of major items. We must address that issue-my Visa card is not the long-term answer to it. Sheilah was able to purchase locally-and we must try to do same.

I believe that NCI must address the issue of almost full-time person to work with VANAC-at least for 6 months until they get it all together. I can do it but I am not NCI person. Ihor cannot deal constantly with the day to day supply problems-which will be acute until VANAC has it under control-if ever. I did deal with it from LLNL in the long ago-and we had a system. I do know that just left to their own devices, VANAC cannot cope with the project requirements. If NCI wants me to deal with supplies as an almost full time job then we need to talk about it. I guess that no one at NCI realized how closely I worked with LLNL -almost daily, and made decisions for them on the spot-since I knew what was required and we could not wait for "committee" OK. We had an approved purchasing list and I helped them to fulfill that list. In addition, LLNL and I dealt with European suppliers with no problems. Sometimes we had to find some piece of equipment in one of several European countries-and Sheilah and staff phoned, faxed, whatever, until we found it and had it delivered. In the past, I received many quotes from European supplies via fax at my home and either Ok d it to Sheilah or told her that it was too much and suggested another price structure. I guess that I am a little chagrined that NCI never seemed to acknowledge the time and expenses which I spent in the early formative years of the Minsk project. I spent countless hours resolving NCI-supply problems for Minsk. NCI knew when they had a good thing, I guess, having a person for free who would render assistance-and I did so because I knew that no one at NCI could do it. Perhaps thor can now understand why I am a little put-out by the laissez-faire attitude which NCI has toward me. Well, I am not complaining and seek no recompense. I have been an almost full-time person-in many regards- but treated like a poor relative who will respond when necessary.

Well, my good friends, and I do count you as my good friends, the time has come for some serious considerations. My role for the projects has been more than the biochemical consultant-more than the NCI-"in house" supply person and more than the "quarterly visiting person". I am not going to walk away from projects but on the other hand, I am not going to perform the duties of an NCI staff person without some role and position in these projects. I do not think that is an unreasonable request.

Regards,

Everett

FAX TRANSMISSION

TO: Burnell R. Brusveen
Team leader, Medical Care Products
VANAC
Fax 708-786-4974

FROM: E. Mincey

Thanks for your letter and attached lists of 1 August.. Dr. Masnyk will return to Washington on Monday, 4 August and I will discuss the contents of your letter with him. We will contact you as soon as he has had a chance to talk with me.

I can comment on some of the issues raised in your letter-and will use some examples which are for discussion purposes and do not constitute a full reply. As I understand it, the attached listed items represent those which you have tried to request quotes but need more descriptive information? I have a copy of the letter and list sent to VANAC by Dr. Masnyk on 14 July and I do not understand what more "descriptive" information can be furnished for these items. In most cases, a suggested supplier was furnished, not as a requirement to use that supplier, but as a source of information about line items-i.e. full descriptions may be found in the relevant suppliers catalog. For some items, no alternative supplier is acceptable. As examples, the calcium analyzers from Ciba-Corning, reagents from Amersham for Amerlite system, reagents from Abbott for IMX, , Anti-TPO from Brahms, etc. cannot be substituted from other suppliers-they should be ordered as described from suppliers listed. Perhaps we should have designated those line items for which no alternative supplier is acceptable.

As a general principle, reagents for analytical systems already in place, or which will be in place in Kiev soon, should be obtained from European sources so that calibration will be in the system used in Europe, Canada and CIS countries-the SI system. In addition, an attempt should be made to arrange reagent supplies for analytical instruments on a "standing order" basis with perhaps quarterly shipments.

With regard to your request for a "statement of work" defining electrical, shipping, etc. I had thought that we were clear on those items during our visit to your facility. Briefly, the electrical requirement for equipment in CIS countries is 220 volts, 50 cycles(Hertz) without exception. This imposes some consideration to obtain items such as freezers, refrigerators, computers, scientific apparatus and the like from European or even local sources in Belarus and Ukraine. Obtaining items from the local economy in the latter countries requires some discussion between your organization and NCI since the mechanism is not clear at this point.

I thought that the covering letter from Dr. Masnyk was clear with regard to delivery addresses in Belarus and Ukraine. The labelling requirements were also clearly outlined.

The mode of transport was discussed during our meeting and I understood that airfreight from Chicago to either Kiev or Minsk was the preferred mode-considering that you had agreed to "stockpile" shipments at your facility awaiting shipment. Lufthansa does well in getting shipments to either city. For supplies which originate in Europe, mostly Germany, the same mode would apply. Supply of labels will be addressed with Dr. Masnyk on Monday but the correct label statements and other "customs" information was well outlined in Dr. Masnyk's letter and must be followed to the letter-without exception.

It is clear that we need to have some more "in depth" discussions between NCI and VANAC which is normal at the outset of such an undertaking. We need to understand what you want from us more fully and what we can do to make your task easier. Full disclosure and cooperation is our goal since some of the Priority 1 supplies are needed very soon. We understand your problems since our items list encompasses everything from computer equipment to simple phlebotomy tubes-it is not an easy task and we know it. We will give your organization whatever help and guidance is required to facilitate the transfer of supplies to our projects in Minsk and Kiev. We expected the first "reading" to raise many questions-and it has. It is normal in a complex undertaking of this sort.

Expect some contact on Monday-Tuesday at the latest about these questions. Thank you for correspondence. By the way, it would help us if you could generate a separate list of those items for which you have a source of supply, as suggested in your letter. We could then concentrate on the items in question.

Regards,
Everett Mincey

Everett Mincey. Ph.D.

Masnyk, Ihor

From: Everett K. Mincey
To: Masnyk, Ihor
Subject: Urinary iodines
Date: Saturday, August 02, 1997 12:43AM

Dear Ihor:

While you have been away I have been a busy person with many emails from Van Middlesworth and others on the international scene. I have a contact in Belgium who wants to send us some "check" samples for urinary iodine. I cannot receive them here in Canada because of customs problems with biological samples. I have told principal in Belgium that we would discuss it and decide where samples should be sent-on a one time basis. What do you think? Send them directly to labs in Minsk and Kiev- or to Van Middlesworth who can get them to VANAC for shipment?

Many things await your return as you will find out. This is not the major item but we need to make sure that samples find their way into the labs in Minsk and Kiev without problems. We have much to discuss when you return-mostly VANAC-and the prompt shipment of supplies to both places. You will see their correspondence to me and reply. We have much hand-holding to do with VANAC-they need to have more concrete guidelines about suppliers and our priorities for shipments. I am not surprised at their response at first reading-but we need to give them more explicit guidelines-it seems. Well, it is a learning experience but we cannot afford too much time for them to learn. Some things have to be sent soon!. I guess that we need to generate a "hot list" of some items for them to ship soonest. We cannot afford to wait while they go out for bids, etc, for many items.

Regards,

Everett

Masnyk, Ihor

From:	Beebe, Gilbert
To:	Masnyk, Ihor; Finch, Dr Stuart
Subject:	Operations Manual
Date:	Tuesday, August 05, 1997 12:01PM

For your information. I'll include Stu's e-mail address in my reply.
Gil

FORWARDED FROM: Beebe, Gilbert
Microsoft Mail v3.0 (MAPI 1.0 Transport) IPM.Microsoft Mail.Note
From: Everett K. Mincey
To: Beebe, Gilbert
Subject: Operations Manual
Date: 1997-08-05 00:06
Priority: 3
Message ID: 2C879F10440DD11864000805FEACCE5

Dear Gil:

I did receive Faxed pages of changes to OM. Will review them and send you comments tomorrow. Have conference call with Ihor and VANAC tomorrow morning-hope we can impress upon them the urgency of some items. I have suggested to Ihor that we can help them in the critical short term by having me deal with some suppliers where we are not going out for bids-just to get some things flowing. I do not want them to dither around with some of the critical items-just get them ordered and on the way soon. Had nice chat with Ihor today-suggested to him that establishing a firm line of supply was the most critical issue at the moment for our projects. I hope that telecon tomorrow can clear the air and we can establish a critical pathway for some supplies to leave for Minsk and Kiev very soon. There are some questions about supplies for Leukemia project-and I do not know who will deal with them from a scientific basis on our side-I can deal with some of them-ie, find suppliers, substitute items, etc. but there are items which should be addressed by Leukemia group-and not by me. I believe that we are going to have to take our Priority 1 list and short list it to those items which are most critical and have VANAC move them without delay. Perhaps the whole list was overwhelming so we should try for an abbreviated list-for immediate shipment?

I hate to go from one crisis to another and desperately want to avoid anymore "emergency" shipments. Ihor mentioned that we may have an arrangement in Kiev which will allow us to purchase some items on the local economy. We need to see what can be done along the same lines in Minsk-although I believe we will have to have a different approach there. I still do not understand why we cannot do the same thing that Sheilah did in Minsk-take some instruments of currency and buy things as needed! Maybe we will have to have someone act as VANAC surrogate but it should be possible to buy things on the local economy in Minsk.

Masnyk, Ihor

From: Beebe, Gilbert
To: Masnyk, Ihor
Subject: Minsk problems
Date: Tuesday, November 04, 1997 9:35AM

FYI, Gil

FORWARDED FROM: Beebe, Gilbert
Microsoft Mail v3.0 (MAPI 1.0 Transport) IPM.Microsoft Mail.Note
From: Everett K. Mincey
To: Beebe, Gilbert
  Gilbert Beebe
  A. Bertrand Brill
  Dr. A.B. Brill
  Robbins, Jacob
Subject: Minsk problems
Date: 1997-11-04 00:59
Priority: 3
Message ID: 927E9D14CB54D111865400805FEACCE5

Dear All:

Received emails from all on this recipient list about Minsk situation. I can go to Minsk as soon as I make a quick turnaround from Kiev. I could go to Minsk as early as end of November and stay until 20th or so of December. I have no valid visa for Belarus at this moment but could enter the country with an invitation and pick up visa ~~at~~ airport. I believe that they still do it in Belarus. Renee can confirm that with Belarussian consulate in Washington. Otherwise, when I return from Kiev on 20th, I can send passport to Washington and wait for visa in passport. With that scenario, I should be able to go in the first week in December.

Saw the major complaint email from Minsk-signed by everyone in Minsk-except Lukashenko. I understand their feelings of frustration-since I have the same feelings. We just have to rethink the laboratory issues, make sure that the supply lines are going to function and monitor supplies closely. If VANAC has trouble with former suppliers of laboratory diagnostic kits, we will have to plan for something different. I have some fall-back possibilities in that case.

I will try to talk to Ihor tomorrow re VANAC and get updated on their efforts. I did send to Ihor information on Chiron calcium analyzers. They phoned me from England and the word I had was that both instruments were being shipped within 10 days(a week ago). I have list of phone numbers and fax numbers from their engineers and representatives in Moscow who are going to provide set-up and ongoing servicing when needed. I faxed that list to Ihor.

I think that I can do more about laboratory supplies from Kiev and Minsk than from here! I have let VANAC do their thing. However, during the LLNL tenure, I became involved through Sheilah with all lab reagent supply companies and we managed to get it on track.

Obviously, we need to do some major fence-mending and soon! Some can be done from Kiev-Minsk if I get on the phone and badger the representatives in Russia of these companies. We cannot run project with these supply deficiencies and we all know that. I know that Ihor has been on top of VANAC and so have I. That is not the complete answer and perhaps a more personalized approach will be necessary. I will have to do it but have been reluctant to interfere with VANAC process up till now.

I see that I have left off Ihor in the address list. My fault but cannot change it now. Gil can show him copy of this communication.

Regards,

Everett

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

12 May, 1998

Memorandum to Those Addressed

Subject: Progress of Phase I, Leukemia Project, Chernobyl Cleanup Workers in Ukraine

Phase I finally started on 1 November, and a first quarterly report was distributed to the NCI-Columbia team that visited in early February. The report is too bulky for distribution but if you are interested in any part of it the organization is as follows where"Milestone" is essentially the "task" defined in the protocol

Epidemiology Group
    Milestone 1 Investigate Registry
        2 Obtain Registry Tabulations
        3 Verify Record Linkage
        4 Begin to Assemble Cohort
Hematology Group .
    Milestone 7 Identify High-Dose Sample
        13 Accumulate Tissues for Banks
        23 Learn Ascertainment, Other (Hematologic) Diseases
        24 Meeting with Hematologists, Oncologists, and Pathologists
        26 Bleed High-Dose Subjects
        27 Obtain and Process Pre-treatment Blood
Dosimetry Group
    Milestone 8 Investigate Dosimetry Sources and Needs
        9 Study Tasks of Cleanup Workers
        11 Inventory Questionnaire Data
        13 Investigate Tooth Sampling
        15 Establish EPR Dosimetry Lab
        16 Do Biological Tests on Bloods
        18 Accumulate Tissues for Banks

The listing does not indicate that the task has been completed, only that some work was done. The progress of the work has been slowed by the absence of critical items of equipment. Dr Masnyk has been extremely busy arranging for the large purchasing department of the Department of Veterans Affairs to take over the procurement functions of LLNL. He has made a great deal of progress but there still are several problems affecting the manipulation of the Chernobyl Registry, the performance of EPR dosimetry, and examining bloods by FISH.

A contract was written with Columbia University, School of Public Health, to provide expert assistance on all phases of the project, and a team of experts from Columbia accompanied NCI staff and consultants on the February trip to Kiev. Some of them will also journey to Kiev next month with the NCI team and French representatives of IPSN which has underwritten the procurement of supplies and equipment for the project.

French colleagues accompanied the NCI team to Kiev in October and again in February. The French team (Dr Margot Tirmarche, epidemiologist, and Phillippe Hubert, physicist) is involved in studies of cleanup workers in the Russian Federation and Belarus and brings a wealth of experience and expertise to the effort.

In March, 1997, representatives of NCI and the French team met in Kiev with investigators working with WHO on leukemia and other problems of the cleanup workers, and completed the development of an interview form and of interviewing procedures designed mainly to obtain information necessary for environmental dose reconstruction. The form is available in English for those want copies.

A batch of published papers and unpublished material on the leukemia project accompanies this note, as follows:
1) Columbia University group site visit, 2/98
2) Review by John Boice of paper by Ivanov et al on leukemia and thyroid disease among cleanup workers in the Russian Federation
3) Bard et al, Chernobyl, 10 Years after: Health Consequences
4) Ivanov et al, Cancer Incidence among Liquidators of the Chernobyl Accident: Solid Tumors, 1986-1995
5) Gluzman, Approaches for Studying Radiation-Induced Leukemia
6) Baverstock, Chernobyl and Public Health
7) Dr Finch's trip report, 2/98
Items 1 and 7 are the most important for understanding the status of the project. They were written for stateside distribution and are not to be shared with our colleagues in Kiev. Dr Finch and I hope that you will continue your interest in the project and that we can keep you fairly well informed during Phase I. At the completion of Phase I, you will recall, we have the task of determining whether Phase II, as roughly described in the Protocol, would be a practical undertaking. This determination will involve not only feasibility but also probable scientific worth. This point is especially relevant because there is as yet, in early 1998, no definite evidence of excess leukemia among the clean-up workers. It would appear that any worthwhile scientific objective for Phase II might be the documentation of negative findings at a specified average dose accumulated over an average period of about two months.

G W Beebe, PhD

Addressees:
Drs Boice, Bouville, Davis, Finch, Howe, Jensen, Littlefield, Magrath, Masnyk, Mitchell, Robison, Tirmarche, Wachholz

# TECHNICAL REPORT
for the period 1 April 1997 to 30 June 1997

I. BelAm Thyroid Study

During this reporting period Dr. N. Krysenko left the project and Dr. V. A. Stezhko was appointed as the new Director of BelAm Project. Dr. Voronetsky resigned from the Epidemiology Group and was replaced by Dr. Buglova.

On the political scene a new Minister of Health was appointed: Dr. Igor Borisovich Zelenkevich.

Activity of the Data Coordinating Center increased substantially, concentrating on selection of the cohort of 3,500 subjects from the middle dose group (0.3 to 1 Gy) and 3,500 from the low dose group (below 0.3 Gy). All high dose individuals are automatically included in the cohort (at present 2,500 were identified from possible catchment of 7,800). During May-June approximately 700 letters were sent out monthly inviting people to participate in the study.

The screening center extended its operation hours to two shifts managing the processing of up to 20 individuals per day. The subjects are examined both in Pediatric Department (for children up to 16 years of age) and in the Adult clinic for those older than 16 years. During this period 301 cohort subjects were examined, 21 of which were referred for further study at the clinic in Aksakovshchina and 4 to Minsk Oncology Department.

Operations of the Central Laboratory were restricted due to the lack of reagents.

Dosimetrists were refining the interview form and developing a self-interview form for the children; these forms are now sent to their homes to help them prepare for the on-site interviews, otherwise the recollection is very poor on what happened "then". Work continued on estimation of the calibration factor for the estimation of iodine activity as a function of the thyroid size and on mathematical models for human body phantoms.

II. UkrAm Thyroid Study.

Due to the new laws passed in Ukraine imposing new taxation and customs fees on all imports, it became necessary to register the project with the Agency for Reconstruction and Development of Ukraine in order to be relieved of the new taxation burden. Official exemption from taxes on equipment and supplies has now been received, and a means to transfer local support without taxation is being negotiated.

The transfer of funds to VANAC occurred in late June; hence, no technical equipment could be delivered to the Institute of Endocrinology and Metabolism in Kiev, Ukraine. This will soon be remedied, however.

By borrowing computer equipment from other organizational units, Dr. Tronko was able to initiate activity at the Data Coordinating Center. Dosimetry data were obtained from Dr. Likhtarev and initial steps were undertaken to establish a cohort.

Pilot examinations were initiated on a small number of patients to evaluate the proposed procedures, the paper flow, interview techniques and the responses of the candidates.

III. UkrAm Leukemia Study

Due to the fact that it was not possible to deliver equipment or supplies to the Research Center for Radiation Medicine in Kiev, Ukraine, no work could be undertaken during this reporting period. Equipment and supplies will be seent soon, however, now that the agareement with VANAC has been completed.

Status of the collaborative projects between Belarus-U.S. and Ukraine-U.S.

25 Oct 96	Official signing of the Protocol for the "Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chernobyl Accident".
6 Dec 96	Signing of the financial arrangement between, the Center for Radiation Medicine, Kyiv, Ukraine and the National Cancer Institute, Bethesda Maryland for local financial support.
23 Dec 96	Signing of the Interagency Agreement between Department of Energy and National Cancer Institute for the joint implementation of the projects "U.S./Belarus/Ukraine" on joint research on the biomedical effects of the Chernobyl reactor accident.
18 Feb 97	Interagency Agreement between the U.S. Nuclear Regulatory Commission and the National Cancer Institute entitled: "Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chernobyl Accident."
18 Feb 97	Interagency Agreement between the U.S. Nuclear Regulatory Commission and the National Cancer Institute entitled: "Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus and Ukraine"
In process	Transfer of funds from DOE to NCI
7 Mar 97	Signing of Letter of Understanding for the extension of the period of the last agreement with the Belarusian Institute of Radiation Medicine and Endocrinology.
7 Mar 97	Release of the RFP for support contract to NCI staff involved in U.S.-Belarus-Ukraine projects.
10 Mar	Draft of Proposal for equipment/supplies procurement and delivery to Department of Veterans Affairs Acquisition Center.
	Planning of the first meeting of Binational Advisory Group to be held in Kyiv and Minsk.

BelAm Thyroid Project Update:

Appointment of new Minister of Health, Dr. Igor Borisovich Zelenkevich. We met him on our last trip and had a satisfactory exchange of views. We were assured of his support for the project.

Project reorganization: The project leadership was expanded from one based on a single institution to several rather independent Institutes that are responsive directly to the Ministry. Dr. Krysenko, one of the Deputy Ministers, continues to be in charge of the project.

The potential of expanding the project to Gomel area is becoming more realistic. We visited this place and found it acceptable for our project, provided that internal organization will be established by the Belarusian authorities.

Most of the originally requested equipment (about 80%) is on site. The remaining requests will be processed as soon as the relationship with VA Acquisition Center will be established.

During January the screening process began in Minsk. To date 58 patients have been entered. Various operational aspects are being modified based on the experience gained.

Work continues on finalization of various forms and operations manuals.

Work on establishment of study cohort continues.

Possible Problems

Political instability in the country may lead to additional changes in personnel and even worsening of our relationship.

The newly created organization has no track record; it will be more difficult to work with than with the old Institute.

Gomel is needed for the expansion of the study; however, Japanese are actively involved in work there. Some compromise/understanding may have to be developed with Japanese to avoid double examination of cohort members, while assuring adequate data exchange.

Several units (epidemiologists, dosimetrists, Data Coordination Center, and possibly Central Laboratory) may have to move to a new location. This may interrupt smooth flow of the operations before they are fully developed.

UkrAm Thyroid Project Update

Institute staff assigned to the project has been officially appointed.

A list of 108,000 names from Chornobyl Registry has been received to be used in cohort selection.

Initial shipment of computers was received by the dosimetrists. Other requests will be attended to as soon as we obtain a relief from taxes and customs which have been introduced recently by a new Agency for Reconstruction and Development (cf. Below under "problems").

Forms and operations manuals based on Belarusian model are in developmental stage.

Initial contact with one of the principal raions in Kyiv Oblast was made with a preliminary trip of a model mobile team to future screening site.

Possible Problems

Organization is still in formative stage. Additional personnel will have to hired, trained.

The cohort is in very initial stages of its formation. Additional contacts with other registries to be made.

There is basically no equipment yet on site that was required for the project.

New Government regulations on taxation and customs of any goods delivered to Ukraine put a virtual stop on any deliveries until a waiver from these regulations is obtained. A mini-van which was delivered in December to be used in transporting mobile screening teams is still being held at the customs offices.

UkrAm Leukemia Project Update

This project is ready to start the operations. However, no equipment has been delivered to them to date. The same customs/tax problems are preventing us from sending any equipment.

Financial aspects

Funding for the leukemia project should be adequate to purchase all requests of first priority. There may be a shortage for the second and third priorities, if the estimated costs (based on commercial catalogues) are not discounted.

Funding for the Ukrainian Thyroid Project should be adequate to cover top priority equipment and reagents for 1-2 years, depending on the final numbers in the cohort and the rate of cohort accession.

Funding for the reagents for Belarus Thyroid Project should be adequate for 1-2 years; there may be some shortfall in providing all the desired equipment for the participating units. Even though we plan for extending the area of operations to Gomel Oblast, at this time we have no funds to equip them adequately.

# TECHNICAL REPORT
for the period 1 July 1997 to 30 September 1997

"Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Project) and in Ukraine (UkrAm Thyroid Project)"

Submitted by: Ihor J. Masnyk, PhD
Radiation Effects Branch
DCB,NCI

1. BelAm Thyroid Study

During this reporting period there were no changes in the project personnel.

Weekly meetings were held with principal staff to review progress, determine directions for further work and correct any shortcomings. One of the recurrent issue concerns quality control measures with which the staff seems to be struggling. An interim decision was reached to make the group leaders responsible for quality control withing their organizational entities.

Work continued on establishment of the study cohort, preliminary location of identified study candidates and assessment of the efficacy of current searches. During this period 2,776 letters were mailed inviting proposed individuals to participate in the study. From the positive responders a schedule for visits to the screening center was developed.

A total of 308 subjects were examined by the screening center during this period; seven thyroid cancers were identified, two of which were discovered for the first time. Central laboratory collected urine and blood specimens and performed analyses until they ran out of reagents. The remaining samples were frozen for future analysis.

Work continued on revision and updating of the Manual of Operations and on the multitude of study forms. Training of select personnel for future employment in the screening program was continued.

Data Coordinating Center participated in coordination of the paper flow, development of additional forms and software for handling the incoming hard copy data. Close cooperation with epidemiologists assured proper development of the cohort and search for individual candidates for the study.

Dosimetrists carried out interviews of all the subjects that were screened and prepared revised estimates of thyroid doses for 30 of those subjects.

2. UkrAm Thyroid Study

In spite of intensified efforts, no equipment or supplies have reached the Institute of Endocrinology and Metabolism during the past quarter. Therefore, no work could be initiated in the areas of screening and clinical laboratory determinations. Most of the activities centered on the organizational aspects of the Data Coordinating Center and Epidemiology where the staff worked with two borrowed work stations in minimally furnished rooms. Work continued in all sections on development of the Manual of Operations, and on various forms and questionnaires.

A program was developed for the selection of preliminary cohort of 20,000 individuals: 10,000 of subjects with thyroid dose higher than 1 Gy, and 5,000 each of persons with doses in the range of 0.3 to 1 Gy and lower than 0.3 Gy. Personal data on 44,000 individuals from the Institute's computer database (Dr. Kravchenko) have been received and are being processed.

In a preparatory fashion, pilot examinations of selected cases were carried out testing the flow pattern as the patients are examined at different stations, the handing of the paperwork, completion of questionnaires and of the interviews, etc.

In preparation for mobile operations later this year (work in Oblasts outside Kyiv), four teams were trained and certified for this work. Materials were prepared to used in publicizing the study through radio, newspapers and lectures to be presented by the Institute staff.

The pathology staff continued to collect pathological material from all patients born after 1968 from oblasts targeted for cohort selection. Material is being stored for possible use when the study gets under way and some of these individuals may fall into the screening group. Then their data will already have been captured.

Dosimetrists participated in development of programs to facilitate the input of the questionnaire results into computerized database. Information was collected of direct thyroid dose measurements in pregnant women searching for useful records to study the question of in utero exposure. Some individuals were measured more than once, so correction techniques had to be developed for proper dose estimates from such data.

TECHNICAL REPORT
for the period from 1 July 1997 to 30 September 1997

"Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chernobyl Accident (UkrAm Leukemia Project)"

Submitted by: Ihor J. Masnyk, PhD
Radiation Effects Branch
DCB, NCI
30 October 1997

As stated in the financial report, the funds for this project were transferred from NRC through the NCI to VA National Acquisition Center (VANAC) only at the end of June 1997. During the summer months the staff at VANAC, in close interactive communication with NCI and our consultant Dr. Everett Mincey, were working hard to contact prospective suppliers to obtain quotes on the desired equipment and supplies. The requests made by our Ukrainian colleagues were based in some cases on outdated catalogs and were not precisely stated to permit specific orders to be placed. Therefore, it was only in September 1997 that individual orders were placed with various vendors and funds were committed for these purchases. No equipment or supplies have reached the Research Center for Radiation Medicine until October. Even then, due to the very tight laws governing release of such goods from customs fees and taxes, it took weeks before specific items began to arrive at the Center. At our last visit, Dr. Romanenko, Director General of the Center and Leukemia Project Director, made a decision to start the project operations on the first of November, 1997. We accepted his proposal and are looking forward to the constant arrival of the ordered equipment and supplies as well as to the implementation of the project itself.

# TECHNICAL REPORT
for the period 1 October 1997 to 31 December 1997

"Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Project) and in Ukraine (UkrAm Project)

Submitted by: Ihor J. Masnyk, PhD
Radiation Effects Branch
DCB, NCI

1. BelAm Thyroid Study

Dr. Elena Buglova was appointed head of the epidemiologic section replacing Dr. Voronetskiy who left the project several months previously. The space became more constricted as the "imminent" move to some other location loomed on the horizon.

Weekly meetings of the staff continued on a reasonably constant rate with seemingly a positive effect, more understanding among various components and better managerial grasp on the operations. One of the hotter topic appears to be the extension of screening activity to Gomel Oblast; the question remains at this time whether a second center will be established there or just a branch with token liaison representation, while the work will continue to be directed from Minsk center.

Increased attention was noted in the area of cohort establishment, especially after arrival of Dr. Buglova. Over 3,000 addresses were entered on the computer and as many invitation letters sent our with over 1,000 replies being received from the filed. Overall to this date over 2,200 consents were obtained in the center and only 32 refusals to participate in this project.

615 subjects were examined during the quarter with a yield of 95 diagnoses of which 11 were cancers, 74 various goiters, the rest thyroiditis and miscellaneous disabilities. The hormonal tests were still inadequate because the control and titration reagents were not supplied by Abbott in spite of repeated attempts of the VANAC staff to assure delivery. Majority of patients exhibited moderate to severe iodine deficiency.

The Data control Center staff worked on cleaning up various forms, at attempts to introduce stricter quality control measures and on analysis of the failure of such controls.

The operations manual was completed and the material was being translated.

The dosimetrists were involved in carrying our the individual interviews designed to elucidate recollections of food intake, residential characteristics, movement, use of preventive KI etc. 615 subjects were interviewed during Sep-Dec period (1281 during the 1997 period). The biggest problem was that the majority of available interviewees were children below 7 years of age at the time of the accident with poor recollection. Forms were sent to the homes of prospective candidates soliciting cooperation of the parents in preparing the answers, but the success was mixed at best.

The screening group, along with the epidemiologists began to contemplate possible adaptation of mobile teams to allow them to reach outlying areas from which many would volunteer for the project but could not afford trips to Minsk and either refused or did not bother answering the invitation letters.

Dr. Cherstvoy continued being incapacitated after his stroke, so the pathology operations were not optimal. The service is being run by his primary assistant with Dr. Cherstvoy's part time attendance.

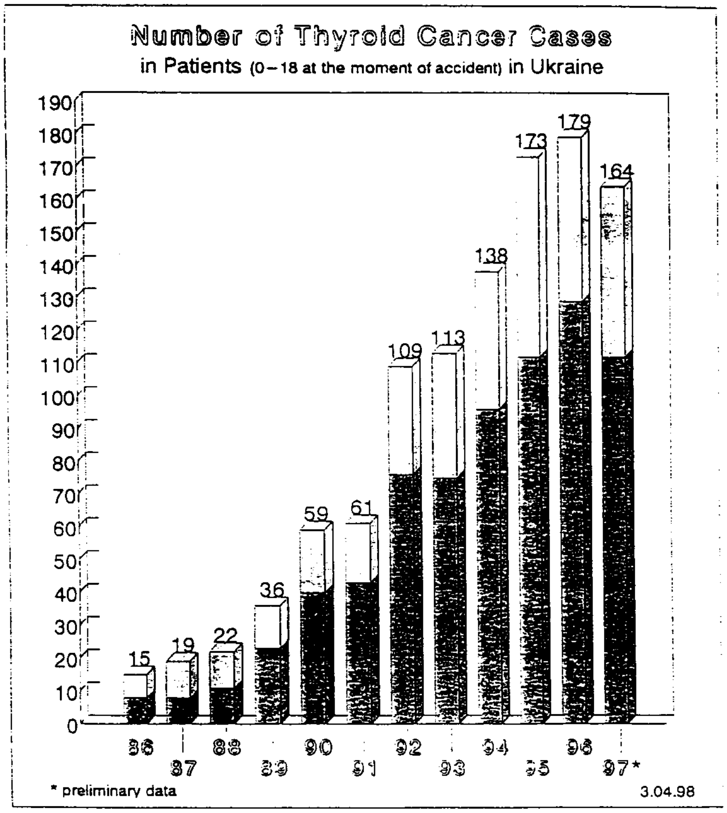
2. UkrAm Thyroid Study

In sopite of the fact that most of the desired supplies and equipment was ordered in the last days of the FY 1997, little beyond the few used computers from NCI have reached the site. As the result, a lot of preparatory paper work was going on along with some informational trips into the country (principally the Ivankiv raion) in anticipation of impending activity. In contrast to Belarus, the project in Ukraine will be predominantly based on mobile teams traveling to different center reaching out for the projected cohort members.

In Ivankiv data was now obtained on 737 cohort members by means of the search of registries as well as cooperation of the local paramedical staff (feldtchers). Arrival of the few computers made it possible to equip the DCC/epidemiology office using also used local furniture.

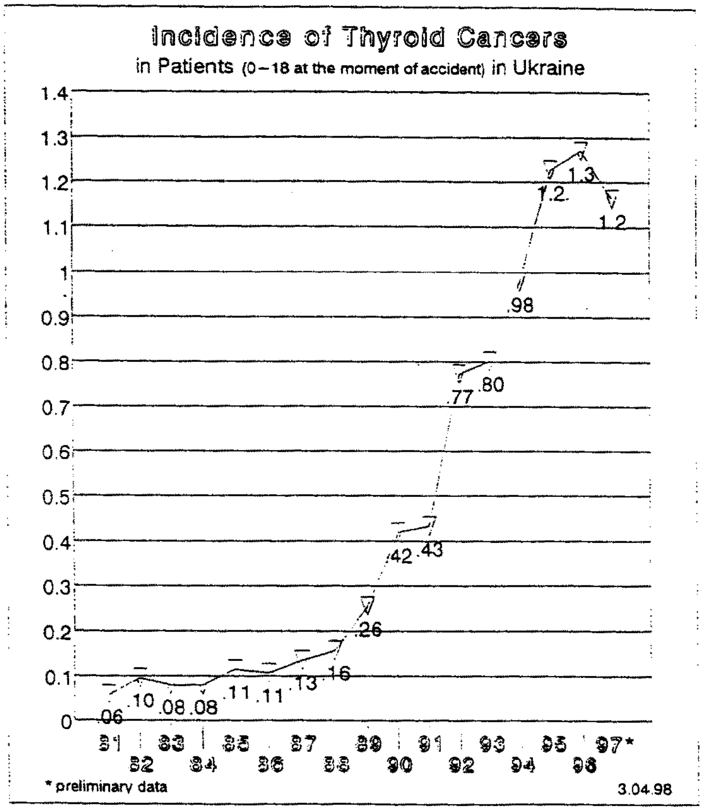
Work continued on the Operations Manual and translation has begun so that by the next quarter it would be available for comments, and eventual implementation.

The pathologist working in this project continued collecting pathological material on patients being treated at the Institute hospital. Although there must be other centers where thyroid problems are being taken care of (for one the children hospitals), this Institute should be the referral center for all thyroid disorders associated with the Chornobyl accident. Work on pathology formes has started and this might be the first area in which the Kiev staff beat the Minsk colleagues.



Darker columns represent figuress for the 0-14 years age group

Work of UkrAm Pathologist; not for distribution; unofficial information only.



Work of UkrAm Pathologist; not for distribution; unofficial information only.

TECHNICAL REPORT
for the period of 1 October 1997 to 31 December 1997

"Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chornobyl Accident (UkrAm Leukemia Project)"

Submitted by: Ihor J. Masnyk, PhD
Radiation Effects Branch
DCB,NCI

Except for a few used computers, it was not possible to deliver the expected supplies and equipment to this project before the end of the year. As a result, the project could not be implemented fully until the last few weeks. Most of the work was preparatory in nature, i.e., development of the cohort, assessment of possible comparison of the several ways of dose estimation (biological and physical dosimetry) and excursions into the field in preparation for the upcoming screening operations (Dnipropetrovsk).

There were no changes in personnel, but a move was anticipated of several units before too long. This will introduce some strain and getting used to new facilities.

In spite of these difficulties, the project was officially started on 1 November 1997.

Status of JCCCNRS Projects Co-Sponsored with NCI and NRC as of October 20, 1997

Ihor Masnyk returned from site visits to Ukraine and Belarus on October 20, 1997. A trip report will be available within two to three weeks. Dr. Masnyk and the team reviewed the three projects (Belarus thyroid, Ukraine thyroid, and Ukraine leukemia studies).

As a result of the scrutiny concerning the results of the Nevada Test Site, Bruce Wachholz has been busy responding to Congressional and intra-agency inquiries. Congress wants to get CDC involved in radiation effects research sponsored by NCI.

NCI selected Columbia University as the new scientific support services contractor on September 30. A kick-off meeting is planned now that Dr. Masnyk has returned from travel to Ukraine and Belarus.

Dr. Masnyk reported that the Veterans Administration National Acquisition Center (VANAC) is in place and working well. NCI chose VANAC to replace LLNL when LLNL discontinued the duties of the purchase, shipment, and delivery of equipment and supplies on the JCCCNRS studies. VANAC has purchased equipment and is now trying to coordinate deliveries.

The Belarus thyroid study now has 700 cases on record (since January 1, 1997). To date, all of these patients are from Minsk. This means that 700 of the 15,000 cohort have been screened for thyroid cancer using ultrasound. The study is doing well, except that researchers are running out of reagents and supplies and there appear to be some difficulties tracing the cohort due to infrastructure problems. Although 20 to 30 patients per day are scheduled, only half keep their appointments. This is attributed to problems with locating the cohort and mail delivery. Letters are not delivered, phone calls are necessary. It is difficult to track people. In addition, access to dosimetry records is difficult because Moscow has the records.

Ukraine appears to be better organized in terms of mail delivery. Records are available in the health system. The names and original addresses are available for searching. However, progress has been hampered by the absence of reagents and supplies. Now that VANAC is operating, it is anticipated that patients will be examined within the next 3 to 6 months for the thyroid study and by April for the leukemia study. By then, the necessary reagents and supplies should be in place. Within the last six months, there were some trial runs with patients. Meanwhile, NCI is setting up agreements with a New York firm to handle the wire transfer payments to Ukraine.

# TECHNICAL REPORT
for the period 1 January 1998 to 31 March 1998

"Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Project) and in Ukraine (UkrAm Project)

Submitted by: Ihor J. Masnyk, PhD
Radiation Effects Branch
DCB, NCI

1. BelAm Thyroid Project

Dr. Sergei Melnov has joined the project staff with responsibilities for liaison with American members of the project, ordering supplies and equipment and communications with NCI staff. He seems to have replaced Dr. Michael Orlov who left on vacations towards the end of last year and has not been heard of.

The "imminent" move of the Institute to another location still hangs over us but at this time only shifts within the building have occurred resulting in somewhat cramped quarters. The fate of the staff working in the dispensary and clinical laboratory n\may be the same, but the time for a move and the location are not yet known.

Reagents are arriving gradually and new requirements are placed on us. There are still shortages, but the most crucial supply of reagents for hormone analysis has been solved. New problems will arise with introduction of mobile teams for outreach of patients that cannot make it to the Minsk dispensary for their examinations.

The screening process continues satisfactory for the present time. About 200 cases are seen monthly. Effort is increasing to expand the catchment area and intensify the effort of notification and follow up on response failures. The forms are undergoing what is seen as final adjustments and the hard copies are being converted to computerized data base.

2. UkrAm Thyroid Study

The infrastructure is ready for field work. The problems still exist in delivery of computers to the DCC and epidemiology sections. This will slow dos\down the overall operation but will not stop the staff from the planned excursions into the field. The actual screening should start in the next quarter. The cohort has been selected from the available registries and invitations are about to be sent out.

A positive development occurred early in the quarter when the Ministry of Health showed increased interest in the project. Meetings with the staff will be held routinely chaired by the Deputy Minister; letters of invitation to participate are signed by the Minister and efforts are under way to allow the candidates to attend screening session by permitting them to take time off from work or school. This support from the highest levels of Ministry of Health should have a very positive effect on the study.

The manual of operations and all the necessary forms have been developed and translated.

A contract was signed with the Science and Technology Canter for Ukraine to act on NCI behalf as the agency for transferring local support funds to the Project. We are approaching final steps of resolving this very complex issue. As a result the project will receive funds free of all taxes.

Difficulties continue at the customs clearance level. The supplier do not always provide proper invoices and this slows down the clearance procedures releasing the recipients from heavy taxes placed on any imported goods. Presently there still exists a problem of "attestation" of any clinical or computer instrumentation, but the locals find various ways of handling it. We cannot do anything about it.

TECHNICAL REPORT
for the period of 1 January 1998 to 31 March 1998

"Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chornobyl Accident (UkrAm Leukemia Project)"

Submitted by: Ihor J. Masnyk, PhD
Radiation Effects Branch
DCB, NCI

The flow of the required equipment and supplies continues to be abominable. The various new regulations and the unwillingness of Eastern European companies to sell on the post-payment basis created a nightmare of paper work requiring assurances that payments will be made, shifts in the delivery dates, led to arguments with various branches of the supposedly American company Computerland, etc. As a result the necessary equipment is still unavailable to the staff, slowing down even the greatest enthusiasts in their attempts at getting the project going.

Addition of some personnel to the VANAC staff and more effective management support gives me a sense of feeling that things will improve soon and before too long all the ordered goods will arrive safely in Kyiv.

Otherwise there exists a "status quo" as of the last quarter report.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

22 July 1998

TECHNICAL REPORT

for the period 1 April 1998 to 30 June 1998

"Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and in Ukraine (UkrAm Project)

Submitted by: Ihor J. Masnyk, Ph.D.
Radiation Effects Branch
DCB, NCI

1. BelAm Thyroid Project

Official Progress Review Site Visit took place 7 June-11 June 1998. The NCI core group was accompanied by the usual team of advisers as well as by new personnel from the Columbia University support contract providing a fresh insight to the project.There were no new appointments in the organization during the past quarter. The move to another location continued to be "imminent", while the staff of the Institute continues working in cramped quarters. The clinical moiety of the group is still operating in the old Dispensary but they too are scheduled to relocate to a new location. Exact time for this could not be established.

A disturbing development surfaced during this visit between the screening group and the Data Coordinating Center (DCC) staff concerning the data entry operations. About 2,700 subjects have been screened, but there was a large backlog of unkeyed records in the Dispensary where the screening is taking place. There seemed to be a "turf battle" between the Dispensary and the DCC that was responsible for the backlog. Operating procedures call for keying on site as much as possible, but the DCC will have to employ some of its resources to help reduce this backlog. Until the data are on the computer BelAm is in no position to prepare the reports that should now be available. Partly because the observations have not been entered in the computer many quality control procedures, which are computer-dependent, have not been activated. There are complaints about the completeness of many study forms. In a large open meeting with the staff these matters were explored and their resolution should be under way.

Locating the study cohort subjects chosen from the list of children with measurements of thyroid radioactivity in 1986 is proving difficult. Substitute can be found for unlocated subjects in the lower dose group, but not in the important high-dose range (>1Gy) unless the Brest sample can be accessed.

An interesting development was reported to us as we were leaving, namely, the thyroid hormone analysis apparatus - the IMX from Abbott - broke down and the repairs would cost around $4,000.00. At present we are trying to determine whether Abbott will take care of this. We never bought this equipment; on the strength of ordering reagents from the, Abbott supplied us with the instrument.

Arrival of equipment and supplies is not as complicated as in Ukraine, but from time to time, the documentation from the vendors is inadequate from the point of view of the customs officials and we have to write explanatory letters.

2. UkrAm Thyroid Project

The Progress Review Site Visit preceded the Minsk Trip (3-6 June 1998). Like in the case of the BelAM project the US team was augmented with various specialists from the Columbia University support contract Organizationally, there were no changes in personnel during this quarter.

Monthly meetings with the representatives from Ukraine's Ministry of Health continued and their interest seemed to have a positive effect on the staff.

As in Belarus, the investigators in Ukraine are having difficulty locating members of the cohort. Fortunately, the numbers potentially available are much larger and the implications, therefore, less critical, provided that steps can be taken to minimize bias associated with the selection of those most readily available for study. The effort to locate subjects has brought to light the apparently poor record-linkage procedures available at the national Chornobyl registry where much of the addresses information must lie. It is hoped that Professor Geoffrey Howe, an expert in record linkage by computer, may be able to improve this situation. Also, until now. the Registry has not had the computing power it really needs. The recent arrival of computer equipment should alleviate this problem.

After some last minute technical difficulties, the local support funds were finally transferred to the STCU accounts and the Institute staff received individual allotments for the past two quarters.

Reagents and equipment continued to arrive. Clearance through the customs varied. On one hand timely notification by us of their arrival to the Institute and the Agency for Reconstruction and Development facilitated the process of clearance; the customs officials, on the other hand, were often requiring clarification of various points. For example a microscope was purchased and its anticipated arrival reported. However, the vendor identified all individual component parts on the invoice rather than just stating that it is the microscope. This then needed to be verified by us before the customs officials released the instrument.

On the positive side, all the computers, FAXes, printers and copiers along with the necessary supplies, programs and some services ordered through Computerland-Kyiv were delivered towards the end of June and cleared through the customs.

Technical quarterly progress report for this quarter has not yet been received as of this writing. As soon as it arrives, it will be forwarded to NRC.

# TECHNICAL REPORT
for the period 1 April 1998 to 30 June 1998

"Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chornobyl Accident (UkrAm Leukemia Project)". Pilot Phase

Submitted by: Ihor J. Masnyk, Ph.D.
Radiation Effects Branch
DCB, NCI

The official Project Review Site Visit was held during 16-21 May 1998 week with a short follow up session during the June trip to the Institute of Endocrinology and Metabolism (UkrAm Thyroid Project). Again the Columbia contract personnel worked closely with the NCI staff on this occasion. The May visit was preceded by a conference in Paris between the NCI and the French Institute of Nuclear Protection and Safety (IPSN) staff. The summary of this session is attached.

The highlight of this visit was a field trip to Dnipropetrovsk and Kryvyi Rih Medical facilities where the study subjects will be enrolled. While the clinical and epidemiologic representatives traveled south, the dosimetrists worked with their counterparts in Kyiv. The summary of the Dnipropetrovsk-Kryvyi Rih visit is attached.

The flow of reagents and equipment increased markedly during this quarter and the problems with the customs were, if anything, even greater than those experienced by the UkrAm Thyroid Project staff. However, it was partially due to a lesser involvement of the Center representative that led to some unnecessary delays. In both locations the difficulty often arose from the fact that various vendors who shipped directly to Kyiv did not include the simple statement on the invoice: "Technical assistance for joint Ukraine-USA Studies".

As in the case of the Institute of Endocrinology and Metabolism, all computers, copiers, FAXes and printers and accompanying supplies ordered through the Computerland-Kyiv have been received towards the end of June. The still outstanding orders of specialized equipment are on track.

The big concern of ours is that relocations are planned for several teams from the Sviatoshyn site of the Center of Radiation Medicine to various less satisfactory locations. This will affect the epidemiologists and dosimetrists primarily and will undoubtedly set them back during the summer months because the new facilities will have to undergo construction changes.

Technical report for the quarter is attached.

Reporting Requirement on Interagency Agreement No. Res-97-001
"Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and in Ukraine (UkrAm Thyroid Project)"
And
"Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chornobyl Accident" (UkrAm Leukemia Project)

Submitted by: Ihor J. Masnyk, Ph.D.
Radiation Effects Branch
DCB, NCI

FINANCIAL REPORT

For the period 1 April 1998 to 30 June 1998

Based on the reports from Veterans Affairs National Acquisition Center, the expenditures for equipment, supplies, shipment and service fees have been tabulated by Projects, categories and costs. Tables are appended. Overall, during this past quarter most of the processed orders were delivered to Belarus and Ukraine and cleared from customs. The remaining non-delivered orders involve specialty productions which, although on track, have not reached the recipients as of this writing.

We anticipate a "steady state" procurement of consumables and replacements during the last quarter under the current Interagency Agreement. It should be noted that there appear to be enough funds for the UkrAm Thyroid project and only limited funds in BelAm Thyroid and UkrAm Leukemia projects. The leukemia activity should be adequately covered for the remaining period of the pilot phase; new funds must be allocated if the study should be extended to a full, long-term project. The Belarusian thyroid project is in need of additional funds, especially if the anticipated expansion to the Gomel area is to be undertaken. The REB staff is currently searching for additional funds.

PROCUREMENT BALANCE SHEET

	Supplies	Instruments	Computers	Fee	Shipment	Total	Balance
UkrAm Thyroid	36,835,14	92,623.26	51,948.92	11,212.34	5,465.09	198,084.75	206,025.25
BelAm Thyroid	40,523.16	56,356.42		5,971.57	2,646.71	105,497.86	75,902.14
UkrAm Leukemia	58,674.57	74,186.28	67,992.72	12,270,01	3,646,71	216,770.29	33,229.71

# GENERAL MANAGEMENT STATUS REPORT
for the period 1 October 1997 to 31 March 1998

Submitted by: Ihor J. Masnyk
REB, DCB
24 April 1998

During the preceding six months the principal attention was directed towards finalization of the transfer of funds from NRC through NCI to VANAC for purchase of equipment and supplies for the three projects being managed by REB staff.

In September massive orders were placed for the sorely needed items in Belarus and Ukraine; before September there was a hiatus of over a year during which no materials was delivered to any of our projects while arrangements were under way for the transfer of funds from LLNL to DOE to NRC to NCI to VANAC.

The support contract with Columbia University was signed during the last days of FY 1997. In November the first post-award site visit was performed by the PO and CO from NCI to Columbia facilities where we met with all investigators proposed for this work and discussed our general plans for the utilization of this contract. The facilities were toured and administrative details discussed with the staff. A briefing conference was held in Bethesda for the individuals from Columbia contract who were to participate in the visit to Ukraine and Belarus thyroid projects. It was well attended and Drs. Beebe, Brill, Bouville, Robbins, Mincey, Mitchell, Wachholz and Masnyk shared their insights and experience with the Columbia staff.

Two program review visits were made during the six months to all three projects (BelAm thyroid, UkrAm thyroid and UkrAm leukemia) to review the progress and plan activities for next quarter. In Belarus clinical examinations have begun and the project proceeds on a modest scale. With proper scale-up, use of proposed mobile teams and possible extension to Gomel (which will require additional funding), the Belarusians should be able to fulfill the protocol requirements. In Kyiv, due to unexpected delays in procuring the necessary equipment and supplies corresponding delays were encountered in both the thyroid and leukemia projects. Both should begin their programs during the next quarter.

Evidently, the massive ordering of supplies and equipment overwhelmed the VANAC's staff and an even flow of the required goods did not materialize. Many of the companies they dealt with did not respond sufficiently rapidly and the governmental procurement regulations slowed down the process of procuring through European companies. However, early this year situation began to improve and a continuous flow of the goods ordered last year was finally established.

New problems surfaced with enactment of new Ukrainian laws on taxation of all imported goods. Both Ukrainian projects had to be registered with the Agency for

Reconstruction and Development of Ukraine to become tax-exempt institutions. This still left the task of clearing every shipment with the customs offices which simply introduced another bureaucratic clearance level and accompanying delays.

Analogous problems occurred in the area of transferring funds for local support to the collaborating staff. After several months of negotiations with the Science and Technology Center for Ukraine, NCI became a partner of that organization and a contract was signed with the Center for the distribution of tax-free stipends to participating staff in both Ukrainian projects.

No such difficulties surfaced to the same level in Belarus as yet.

During this period financial arrangements were renegotiated for continued support to the Belarus and Ukraine thyroid projects.

One meeting of the US-French Technical Steering Committee was held in preparation for the site visit to Ukraine. The French IPSN donated $250,000 for purchase of equipment and supplies for the leukemia project and French representatives began to attend with NCI staff the leukemia program review session in Ukraine.

ATTACHMENT

32

Dr. [illegible]
NIH conference
10 Sep. 98

CHORNOBYL
(Chernobyl)

Cooperative Research Program
between
The United States
and
Belarus and Ukraine

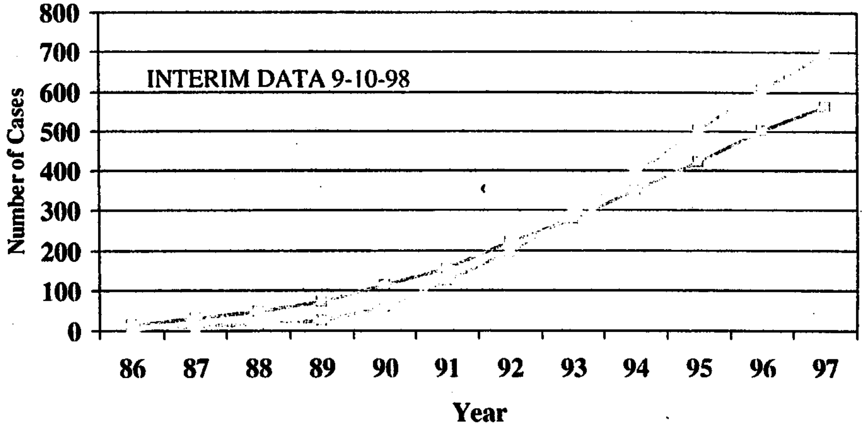
September 10, 1998

9/10/98

Background

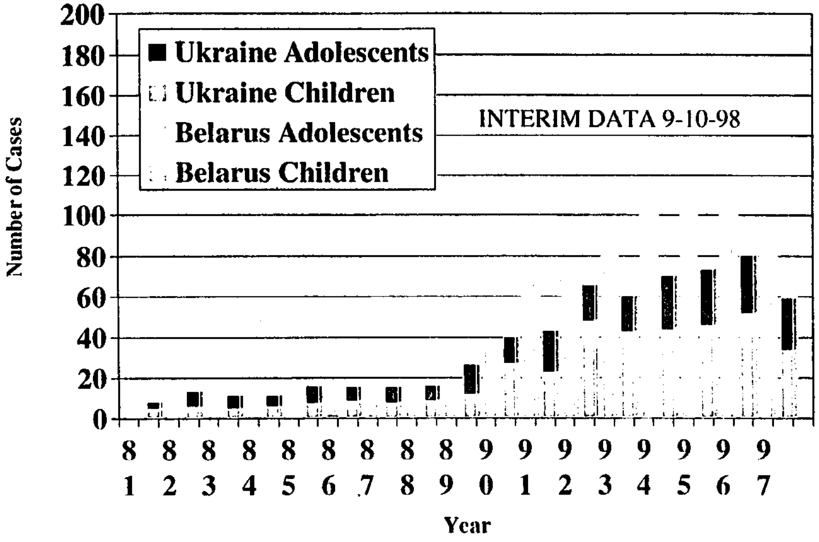
- Presidents Reagen and Gorbachev (1987)
- Joint Coordinating Committee on Civilian Nuclear Reactor Safety (1988)
  - Nuclear Regulatory Commission (NRC)
  - Department of Energy (DOE)
- DOE - Two Sub-Committees (1989)
  - Environment
  - Health
    - Thyroid Disease - Especially Cancer in Children
    - Leukemia - In Clean-up Workers
- DOE - NCI Interagency Agreement (1990)
  - Develop Research Protocols
    - Long-term Follow-up Studies of Thyroid Cancer in Children
    - Leukemia Among "Liquidators" (Clean-up Workers)
- Funding: DOE-NRC-NCI

Number of Thyroid Cancer Cases in Belarus and Ukraine
(Age 0-18 Years)



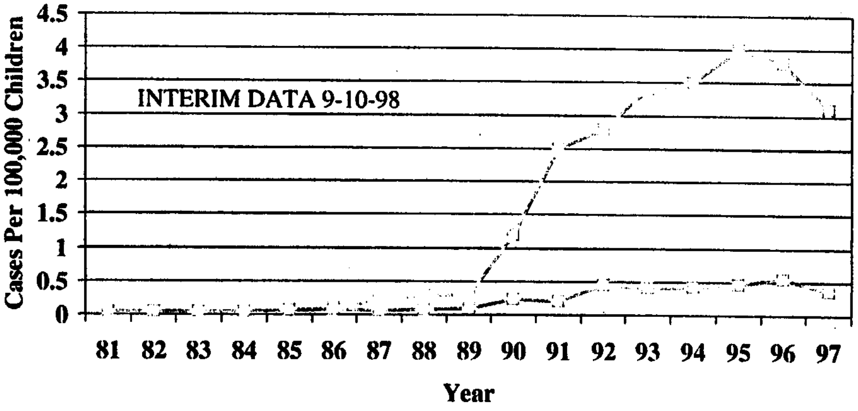
9/10/98

Cases of Thyroid Carcinoma Diagnosed in Belarus and Ukraine in Children (Age 0-14) and Adolescents (Age 15-18) Before and After the Chornobyl Accident



9/10/98

Incidence of Thyroid Cancers in Ukraine and Belarus Among Children (Age 0-14)



9/10/98

Thyroid Studies

- Risk of Thyroid Cancer from I-131
- I-131 Released from
  - – Windscale, England (1957): ~20,000 Ci
  - – Three Mile Island, U.S. (1979): ~15 Ci
  - – Chornobyl, Ukraine (1986): ~30 x 10^6 Ci
    - > 10^6 Children Exposed
    - > 10^5 Children's Thyroids Measured
- U.S. Nuclear Weapons Facilities
  - – Hanford, WN (1944-1972): ~0.7 x 10^6 Ci
  - – Nevada Test Site (1951-1970): ~1.5 x 10^8 Ci

9/10/98

Thyroid Cohort Studies
Objectives

- Dose-and Time-Related Morphologic and Functional Changes in Children Exposed to Radioactive Materials Released from Chornobyl
- Risk Estimates for Cancer and Nodules as a Function of Dose in Relation Both to Sex and Age in 1986
- Comparison of the Relative Effectiveness of I-131 with that of X-Ray and Gamma Irradiation

9/10/98

Thyroid Cohort Studies
Belarus and Ukraine

- Cohort (Belarus: ~15,000; Ukraine: ≥30,000)
  - In Utero - Age 18 at Time of Accident
  - Measurement of Thyroid in 1986
- Annual/Biennial Thyroid Examinations
  - Ultrasound
  - Palpation
  - Laboratory Tests
  - Fine Needle Aspiration (as indicated)
- Dose Reconstruction
  - 1986 Thyroid Measurements
  - Exposure History
  - Environmental Data

Thyroid Dose Distribution
from the Chornobyl Accident
Among Children with Thyroid Measurements

INTERIM DATA 9-10-98

Estimated Dose (Gy)	**Belarus**		**Ukraine**	
	Number	Percent	Number	Percent
0-0.3	13,418	41.9	45,938	60.3
0.3-1	10,381	32.4	19,293	25.3
1-2	4,101	12.8	5,684	7.5
2-5	2,901	9.1	3,698	4.9
5-10	794	2.5	1,012	1.3
>10	416	1.3	530	0.7
TOTAL	32,011		76,155	

9/10/98

Status Of Thyroid Studies

	Belarus	Ukraine
Peer Review	✓	✓
IRB	✓	✓
Protocols Signed	May, 1994	May, 1995
Operations Manuals	✓	✓
Equipment/Supplies (Ongoing)	✓	✓
Examination of Subjects	2,869	529
Dose Reconstruction:		
• 1986 Thyroid Measurement	Initial results available; reanalysis in progress	
• Exposure History	2,869	529
• Environmental Data	To be used to develop an independent method of dose assessment	
Bi-national Committees	✓	✓

9/10/98

Participants

(Agencies)

NCI

- Division of Cancer Biology (Faye C. Austin, Ph.D.)
    - Radiation Effects Branch (Bruce W. Wachholz, Ph.D.)
- Division of Cancer Epidemiology and Genetics (Joseph Fraumeni, M.D.)
    - Radiation Epidemiology Branch (Gilbert Beebe, Ph.D.)

DOE

- Deputy Assistant Secretary for Environment, Safety and Health (Paul Seligman, M.D.)
    - Office Of International Health (Frank Hawkins)

NRC

- Office of Executive Director of Operations (Joseph Callan)
    - Office of Research (Schlomo Yaniv, Ph.D.)

Department of Veterans Affairs

- Veterans Affairs National Acquisitions Center (Philip Naas)

EPA

- Office of Radiation and Indoor Air (Dale Hoffmeyer)

9/10/98

Participants

(Operations)

NCI

- Ihor Masnyk, Ph.D. - U.S. Project Director (DCB/REB)
- Gilbert Beebe, Ph.D. - Epidemiology (DCEG/REB)
- Andre Bouville, Ph.D. - Dosimetry (DCB/REB)

NIDDK

- Jacob Robbins, M.D. - Endocrinology

CONSULTANTS

- A. Bertrand Brill, M.D., Ph.D. - Nuclear Medicine, Ultrasound
- Stuart Finch, M.D. - Radiation Hematology
- Everett Mincey, Ph.D. - Biochemistry
- Herman Mitchell, Ph.D. - Data Management, Computer Science
- Paul Voilleque - Dose Reconstruction

CONTRACTOR

- Columbia University School of Public Health
  Geoffery Howe, Ph.D., Head, Division of Epidemiology, P.I.

9/10/98

Dr. G. Howe
Columbia Univ.
9/10/98
NIH Conf.

SCIENTIFIC SUPPORT FOR THYROID AND LEUKEMIA STUDIES

1. COLUMBIA UNIVERSITY:

A. School of Public Health	Epidemiology Biostatistics Data Management
B. Faculty of Medicine (Cancer Center)	Endocrinology Ultrasonography Cytology Clinical Laboratory Management Hematology Pathology
C. Faculty of Medicine (Center for Radiological Research)	Radiology Biological Dosimetry

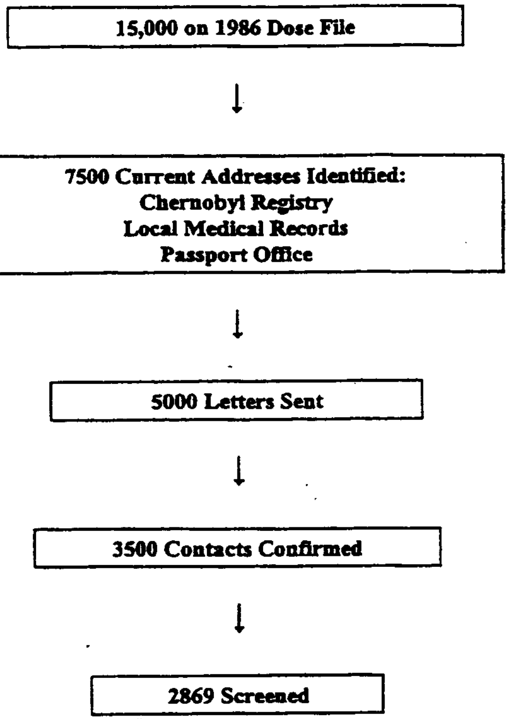
2. UNIVERSITY OF UTAH:

Center for Applied Dosimetry	Physical Dosimetry

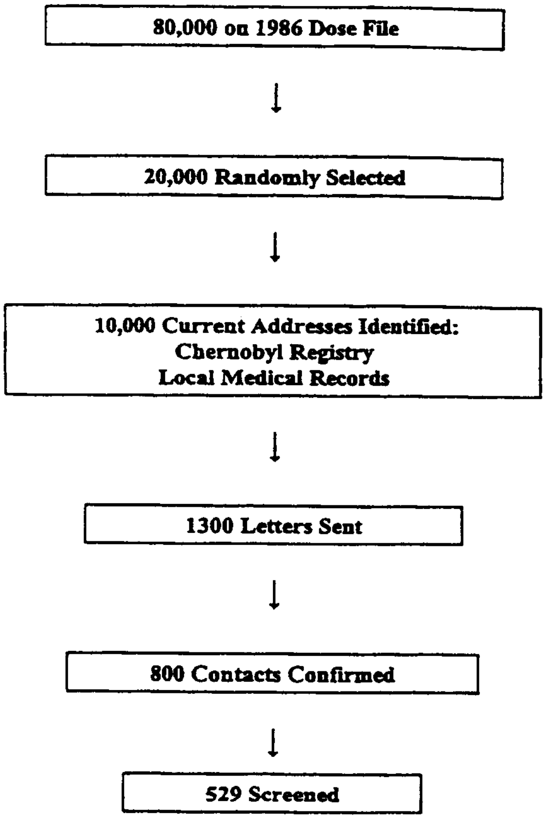
SCIENTIFIC SUPPORT FOR THYROID AND LEUKEMIA STUDIES: PERSONNEL

Epidemiology	G. Howe, Principal Investigator D. Burch
Biostatistics	D. Heitjan
Data Management	D. Heitjan G.R. Howe
Endocrinology	R. McConnell
Ultrasonography	(J. Fayter)
Cytology	E. Greenebaum
Clinical Laboratory Management	D. Fink
Hematology	R. Reiss
Pathology	(A. Matsushima)
Radiology	C. Medvedovsky B. Worgul
Biological Dosimetry	C. Geard T. Straume (Univ. of Utah)
Physical Dosimetry	E. Haskell (Univ. of Utah) T. Straume (Univ. of Utah)

Recruitment of Cohort in Belarus, Current Status



Recruitment of Cohort in Ukraine, Current Status



Examination Schedule

1. Examinations carried out in fixed centers and mobile units.

2. Schedule:
   palpation, laboratory tests (ionized calcium, thyroid stimulation hormone (TSH), urinary iodine), ultrasound, and epidemiology/dosimetry questionnaire.

3. Further evaluation:
   A. If nodule found, fine needle aspiration biopsy performed on all suspicious nodules >5 mm.
   B. If nodule suspicious for malignancy based on clinical, sonographic or cytologic findings, surgery performed.

Initial Pathology Findings, Belarus

Thyroid Cancer	30
Suspicious for Thyroid Cancer	1
Thyroid Adenoma	1
Nodular Goiter (solitary)	103
Multinodular Goiter	8
Diffuse Goiter	76
Combined Goiter	1
Autoimmune Thyroiditis	19

Based on 1,981 examinations

Initial Pathology Findings, Ukraine

Diffuse Goiter, Grade 1	48
Diffuse Goiter, Grade 2	3
Nodular Goiter, Grade 1	9
Multinodular Goiter, Grade 1	3
Autoimmune Thyroiditis	3

Based on 529 examinations

PARAMETERS OF LINERA RELATIVE RISK MODEL FOR THYROID CANCER ACUTE EXTERNAL EXPOSURES TO GAMMA AND X-RAYS
BASED ON COMBINED DATA FROM 7 STUDIES (RON ET AL 1995)
AS PROVIDED BY DR. J. LUBIN, U.S. NATIONAL CANCER INSTITUTE
FEBRUARY 1996

Parameter		Estimate
Main Effect (β)		12.4 per Sievert
Age at Exposure, Years (multiplicative factor):		
	0-4	1.0
	5-9	0.6
	10-14	0.2
Time Since Exposure, Years (multiplicative factor):		
	<30	1.0
	≥30	0.3

OBSERVED AND "EXPECTED" EXCESS OF THYROID CANCER AMONGST CHILDREN EXPOSED TO ^{131}I

Expected Values Calculated From Risks Based on Studies of Acute Doses of External Radiation

Study	Observed	Expected[a]
Swedish diagnostic	0.9	20.3
FDA	2.6	19.0
Nevada Test Site	2.6	2.6
Marshall Islanders	4.8	17.5
Total	10.9	59.4

Estimated Relative Biological Efficiency 10.9/59.4 = 0.18

[a] Excess Risk = 4.0/10^4 person years gray

Power to Detect Statistically Significant Dose Response Relationship

	Belarus	Ukraine
Sample Size	15,000	50,000
Relative Biological Effect:		
1.0	99%	99%
0.33	84%	97%
0.16	64%	84%

Follow-up: 15 years
Linear excess relative risk model
α one-sided: 0.05

Ability to Discriminate Amongst Relative Biological Effectiveness Factors

	Belarus	**Ukraine**
Sample Size	15,000	50,000
Relative Biological Effect:		
0.33	0.1-1.6	0.13-0.83
0.16	0.0-0.9	0.06-0.46

Follow-up: 30 years
Linear excess relative risk model
Expected 95% Confidence Interval

ATTACHMENT

33

CHERNOBYL CANCER STUDIES

FUNDING FOR THE NCI-MANAGED CHERNOBYL STUDIES

The attached tables present a breakdown of the funding contributed by the Nuclear Regulatory Commission (NRC), the Department of Energy (DOE), and the National Cancer Institute (NCI) in support of the U.S. agreement with the U.S.S.R. to study the results of the Chernobyl accident. The Joint Coordinating Committee on Civilian Nuclear Reactor Safety (JCCCNRS) established several working groups to implement the agreement, including Working Group 7, whose mandate included studying the environmental transport of radiation and the health effects of the accident. The three Chernobyl cancer studies currently being managed by NCI were designed to implement some of the research identified by Working Group 7. A brief description of the tables follows.

Table 1 shows that total funding of $11.5 million has been spent to support JCCCNRS and the three epidemiological studies currently being managed by NCI from FY 1990 through FY 1998.

Table 2 breaks down the $5.2 million funding to support the JCCCNRS Working Group 7 by agency.

Table 3 breaks down the $6.3 million total funding by agency between FY 1990 and FY 1998. This table includes funding from DOE, NCI, NRC, and IPSN of France.

Table 4 breaks down the $757,000 in funding by agency (DOE and NCI) used to support the NCI-managed cancer studies between FY 1990 and FY 1993.

Table 5 breaks down by agency the $5.5 million in funding provided between FY 1994 and FY 1998. This table includes funding from DOE, NCI, NRC, and IPSN of France.

Table 6 shows the percentage of each agency's funds that were spent between FY 1990 and FY 1993 and between FY 1994 and FY 1998 by category of expenditure.

Table 7 compares DOE's records of funding with NCI's records of the amounts available and spent each year from FY 1990 through FY 1998.

JCCCNRS and Chernobyl Cancer Studies Funding **Table 1**

FY 1990 through FY 1998

JCCCNRS	$5,193,000
Chernobyl Cancer	6,298,000
Total	$11,491,000

TABLE 2

JCCCNRS - Working Group 7
Other Funding by Agency

FY 1990 through FY 1998

DOE	$4,693,000
NRC	500,000
Total	$5,193,000

Chernobyl Cancer Studies Funding by Agency

TABLE 3

FY 1990 through FY 1998

DOE	$2,422,000
NCI	2,626,000
NRC	1,000,000
IPSN (France)	250,000
Total	$6,298,000

Chernobyl Cancer Studies Funding by Agency

TABLE 4

FY 1990 through FY 1993

DOE	$472,000
NCI	285,000
Total	$757,000

Chernobyl Cancer Studies Funding by Agency

TABLE 5

FY 1994 through FY 1998

DOE	$1,950,000
NCI	2,341,000
NRC	1,000,000
IPSN (France)	250,000
Total	$5,541,000

TABLE 6

Chernobyl Cancer Studies

How Funds Were Spent

Category	Funding Agency	FY90-93 % Spent	FY94-98 % Spent
Equipment & Supplies - Thyroid	NRC	---	100%
Equipment & Supplies - Leukemia	IPSN	---	100%
Contractual Services (Other)[1]	DOE	77%	54%
	NCI	89%	55%
Columbia University Contract	DOE	---	27%
	NCI	---	34%
Travel	DOE	22%	11%
	NCI	10%	6%
Local Assistance	DOE	---	7%
Other[2]	DOE	1%	1%
	NCI	1%	5%

---

[1] Includes a support service contract which NCI had for foreign travel. We were unable to determine, within the timeframe allowed, exactly how much of this category was spent on foreign travel.

[2] Includes supplies and materials, transportation of things, and printing.

TABLE 7

DOE Funds to NCI by Fiscal Year

Fiscal	DOE Records[1]				NCI Records	
Year	Obligated	Carryover	Available	Spent	Available[2]	Spent[3]
1990	100,000	0	100,000	0	100,000	0
1991	0	100,000	100,000	100,000	0	100,000
1992	0	0	0	0	172,000	171,187
1993	372,000	0	372,000	152,570	200,000	199,627
1994	200,000	219,430	419,430	90,000	200,000	196,367
1995	250,000	329,430	579,430	183,804	250,000	159,809
1996	0	395,625	395,625	0	0	95,010[4]
1997	540,000	395,625	935,625	230,373	540,000	540,000[5]
1998	800,000[6]	705,252	1,505,252	685,973	800,000	650,085
TOTAL	**2,262,000**			**1,442,720**	**2,262,000**	**2,112,085**

TABLE 7

Notes for Table 7:

[1] DOE information was provided by the Office of the Chief Financial Officer and was taken from the Financial Information System (FIS) Status of Obligational Authority reports as of September 30th of each fiscal year 1990 through 1997. Fiscal year 1998 data is as of August 31, 1998.

[2] This data was taken from NIH's Interagency Agreements and NIH form #1742 for each fiscal year.

[3] This data was taken from NIH's Summary Object Class Listings for each common accounting number (CAN) used for the DOE reimbursable funds from fiscal year 1992 through 1997. The fiscal year 1998 data is as of 9/1/98. The fiscal year 1990 and 1991 data is taken from early correspondence and information provided by NCI.

[4] NCI was told by DOE that it could spend up to $150,000 of its carryover funds during fiscal year 1996 and NIH form #1742 shows this amount for that year. However, NCI has now found that it did not really have this much available in carryover funds. NCI charged costs totalling $140,515 to the DOE reimbursable CAN in FY 1996, however NCI has now deobligated $45,505 of these costs and charged these costs to their internal Chernobyl CAN.

[5] NCI originally charged costs totalling $929,749 to the DOE reimbursable CAN in FY 1997. However, NCI found that its budget office had mistakenly increased the obligations in this CAN by $822,000, when processing a modification to the previous interagency agreement, with DOE. NCI has deobligated $389,749 from the DOE reimbursable CAN and charged these costs to its internal Chernobyl CAN for FY 1997.

[6] DOE told NCI in August that it would provide $800,000 for its portion of the fiscal year 1998 Interagency Agreement, however as of August 31, 1998, DOE's financial system shows that no funds have been obligated so far in fiscal year 1998. We have included it here because we were told by DOE that it planned to obligate these funds in FY 1998.

ATTACHMENT

34

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

December 15, 1997

Professor Nikolai D. Tronko
Director, Research Institute of
Endocrinology and Metabolism
69, Vyshgorodskaya Street
252114 Kiev
Ukraine

Dear Professor Tronko:

It was a pleasure to meet with you and your senior staff while I was in Kiev last month.

The meeting at the Science and Technology Center in Ukraine (STCU) was informative for all of us; it is encouraging to learn that the services that the STCU can provide will help to solve the problems associated with the receipt of local financial assistance by the Institute for Endocrinology and Metabolism (IEM). It is expected that you are responding to the STCU with the necessary information so that the agreement between the National Cancer Institute (NCI), STCU and IEM can be signed as soon as possible and that the Funding Agreement that you and I signed can then be implemented with no further interruption of financial support.

I cannot overemphasize, however, the importance of the message I conveyed to you at our last meeting – that this is a critical time, and that the level of continued future support will be determined by the level of progress that will be achieved by mid-1998. With the arrival of computers and other clinical and diagnostic equipment, as well as the previous receipt of a vehicle, there should be no reason why rapid progress in the implementation of the project cannot be made.

Although all aspects of the project are important, the highest priority, at the present time, should be given to the identification and location of the cohort. Unless an adequate cohort of subjects that will satisfy the objectives of the project is identified and located, we will have difficulty justifying continuation of the present joint study as we are under continued pressure to show results of our support. I would encourage you in the strongest possible terms, therefore, as we discussed in our meeting, that over the next 6-8 months every effort be made to identify and locate the cohort. As we discussed, this must, if necessary, take precedence over other aspects of the project, even if personnel and financial resources must be reallocated to achieve this objective. It is therefore vital to structure your tasks and milestones in such a way that adequate staff, time and effort can be devoted to this basic requirement. We can all review progress on this matter in depth in February during the next visit of my colleagues, who will be pleased to provide you with any assistance that they can offer.

If the cohort is not adequate and the objectives of the study, as defined in the protocol, are unlikely to be obtained, the NCI (together with the Department of Energy and the Nuclear Regulatory Commission) will need to reassess its commitment to and support for continuation of the current protocol. There is little doubt that the IEM possesses the personnel and capability to carry out this project if there is a commitment of project support, guidance and coordination by the senior management within the IEM.

Please also accept and extend to our project colleagues our personal best wishes for the forthcoming holiday season, and may the new year be bright with promise and filled with personal and professional accomplishments.

Sincerely,

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

P.S. I share in the concerns expressed above by Dr. Wachholz.

Ihor J. Masnyk, Ph.D.
Special Expert

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

December 22, 1997

Dr. V.A. Stezhko
BelAm Thyroid Disease Project Director
Clinical Institute of Radiation Medicine and Endocrinology
23 Masherova Street
Minsk, Belarus

Dear Dr. Stezhko:

It was a pleasure to meet with you and the senior staff of the project while I was in Minsk last month, and to join with you in signing the Funding Agreement for continued financial support.

Our meetings at both the Ministry of Health and the Clinical Research Institute of Radiation Medicine and Endocrinology (CRIRME) were candid and informative. I cannot overemphasize, however, the importance of the message I conveyed to you at our last meeting - that this is a critical time, and that the level of continued future support will be determined by the level of progress that will be achieved by mid-1998. With the arrival of clinical and other diagnostic equipment and supplies, there should be no reason why rapid progress in the implementation of the project cannot be made.

Although all aspects of the project are important, the highest priority, at the present time, should be given to the identification and location of the cohort. Unless an adequate cohort of subjects that will satisfy the objectives of the project is identified and located, we will have difficulty justifying continuation of the present joint study as we are under continued pressure to show results of our support. I would encourage you in the strongest possible terms, therefore, as we discussed in our meeting, that over the next 6-8 months every effort be made to identify and locate the cohort. This must, if necessary, take precedence over other aspects of the project, even if personnel and financial resources must be reallocated to achieve this objective. It is therefore vital to structure your tasks and milestones in such a way that adequate staff, time and effort can be devoted to this basic requirement. We can all review progress on this matter in depth in February during the next visit of my colleagues, who will be pleased to provide you with any assistance that they can offer.

If the cohort is not adequate and the objectives of the study, as defined in the protocol, are unlikely to be obtained, the NCI (together with the Department of Energy and the Nuclear Regulatory Commission) will need to reassess its commitment to and support for continuation of the current protocol. There is little doubt that the CRIRME possesses the personnel and capability to carry out this project if there is a commitment of project support, guidance and coordination by the senior management within the CRIRME.

Please also accept and extend to our project colleagues our personal best wishes for the forthcoming holiday season, and may the new year be bright with promise and filled with personal and professional accomplishments.

Sincerely,

Bruce W. Wachholz

Bruce W. Wachholz, Ph.D.
Chief, Radiation Effects Branch

P.S. I share in the concerns expressed above by Dr. Wachholz.

Ihor J. Masnyk, Ph.D.
Special Expert

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

22 July 1998

TECHNICAL REPORT

for the period 1 April 1998 to 30 June 1998

"Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and in Ukraine (UkrAm Project)

Submitted by: Ihor J. Masnyk, Ph.D.
Radiation Effects Branch
DCB, NCI

1. BelAm Thyroid Project

Official Progress Review Site Visit took place 7 June-11 June 1998. The NCI core group was accompanied by the usual team of advisers as well as by new personnel from the Columbia University support contract providing a fresh insight to the project.There were no new appointments in the organization during the past quarter. The move to another location continued to be "imminent", while the staff of the Institute continues working in cramped quarters. The clinical moiety of the group is still operating in the old Dispensary but they too are scheduled to relocate to a new location. Exact time for this could not be established.

A disturbing development surfaced during this visit between the screening group and the Data Coordinating Center (DCC) staff concerning the data entry operations. About 2,700 subjects have been screened, but there was a large backlog of unkeyed records in the Dispensary where the screening is taking place. There seemed to be a "turf battle" between the Dispensary and the DCC that was responsible for the backlog. Operating procedures call for keying on site as much as possible, but the DCC will have to employ some of its resources to help reduce this backlog. Until the data are on the computer BelAm is in no position to prepare the reports that should now be available. Partly because the observations have not been entered in the computer many quality control procedures, which are computer-dependent, have not been activated. There are complaints about the completeness of many study forms. In a large open meeting with the staff these matters were explored and their resolution should be under way.

Locating the study cohort subjects chosen from the list of children with measurements of thyroid radioactivity in 1986 is proving difficult. Substitute can be found for unlocated subjects in the lower dose group, but not in the important high-dose range (>1Gy) unless the Brest sample can be accessed.

An interesting development was reported to us as we were leaving, namely, the thyroid hormone analysis apparatus - the IMX from Abbott - broke down and the repairs would cost around $4,000.00. At present we are trying to determine whether Abbott will take care of this. We never bought this equipment; on the strength of ordering reagents from the, Abbott supplied us with the instrument.

Arrival of equipment and supplies is not as complicated as in Ukraine, but from time to time, the documentation from the vendors is inadequate from the point of view of the customs officials and we have to write explanatory letters.

2. UkrAm Thyroid Project

The Progress Review Site Visit preceded the Minsk Trip (3-6 June 1998). Like in the case of the BelAM project the US team was augmented with various specialists from the Columbia University support contract Organizationally, there were no changes in personnel during this quarter.

Monthly meetings with the representatives from Ukraine's Ministry of Health continued and their interest seemed to have a positive effect on the staff.

As in Belarus, the investigators in Ukraine are having difficulty locating members of the cohort. Fortunately, the numbers potentially available are much larger and the implications, therefore, less critical, provided that steps can be taken to minimize bias associated with the selection of those most readily available for study. The effort to locate subjects has brought to light the apparently poor record-linkage procedures available at the national Chornobyl registry where much of the addresses information must lie. It is hoped that Professor Geoffrey Howe, an expert in record linkage by computer, may be able to improve this situation. Also, until now, the Registry has not had the computing power it really needs. The recent arrival of computer equipment should alleviate this problem.

After some last minute technical difficulties, the local support funds were finally transferred to the STCU accounts and the Institute staff received individual allotments for the past two quarters.

Reagents and equipment continued to arrive. Clearance through the customs varied. On one hand timely notification by us of their arrival to the Institute and the Agency for Reconstruction and Development facilitated the process of clearance; the customs officials, on the other hand, were often requiring clarification of various points. For example a microscope was purchased and its anticipated arrival reported. However, the vendor identified all individual component parts on the invoice rather than just stating that it is the microscope. This then needed to be verified by us before the customs officials released the instrument.

On the positive side, all the computers, FAXes, printers and copiers along with the necessary supplies, programs and some services ordered through Computerland-Kyiv were delivered towards the end of June and cleared through the customs.

Technical quarterly progress report for this quarter has not yet been received as of this writing. As soon as it arrives, it will be forwarded to NRC.

# TECHNICAL REPORT
for the period 1 April 1998 to 30 June 1998

"Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine Following the Chornobyl Accident (UkrAm Leukemia Project)". Pilot Phase

Submitted by: Ihor J. Masnyk, Ph.D.
Radiation Effects Branch
DCB, NCI

The official Project Review Site Visit was held during 16-21 May 1998 week with a short follow up session during the June trip to the Institute of Endocrinology and Metabolism (UkrAm Thyroid Project). Again the Columbia contract personnel worked closely with the NCI staff on this occasion. The May visit was preceded by a conference in Paris between the NCI and the French Institute of Nuclear Protection and Safety (IPSN) staff. The summary of this session is attached.

The highlight of this visit was a field trip to Dnipropetrovsk and Kryvyi Rih Medical facilities where the study subjects will be enrolled. While the clinical and epidemiologic representatives traveled south, the dosimetrists worked with their counterparts in Kyiv. The summary of the Dnipropetrovsk-Kryvyi Rih visit is attached.

The flow of reagents and equipment increased markedly during this quarter and the problems with the customs were, if anything, even greater than those experienced by the UkrAm Thyroid Project staff. However, it was partially due to a lesser involvement of the Center representative that led to some unnecessary delays. In both locations the difficulty often arose from the fact that various vendors who shipped directly to Kyiv did not include the simple statement on the invoice: "Technical assistance for joint Ukraine-USA Studies".

As in the case of the Institute of Endocrinology and Metabolism, all computers, copiers, FAXes and printers and accompanying supplies ordered through the Computerland-Kyiv have been received towards the end of June. The still outstanding orders of specialized equipment are on track.

The big concern of ours is that relocations are planned for several teams from the Sviatoshyn site of the Center of Radiation Medicine to various less satisfactory locations. This will affect the epidemiologists and dosimetrists primarily and will undoubtedly set them back during the summer months because the new facilities will have to undergo construction changes.

Technical report for the quarter is attached.

Reporting Requirement on Interagency Agreement No. Res-97-001
"Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid
Project) and in Ukraine (UkrAm Thyroid Project)"
And
"Study of Leukemia and Other Hematologic Diseases Among Cleanup Workers in Ukraine
Following the Chornobyl Accident" (UkrAm Leukemia Project)

Submitted by: Ihor J. Masnyk, Ph.D.
Radiation Effects Branch
DCB, NCI

FINANCIAL REPORT

For the period 1 April 1998 to 30 June 1998

Based on the reports from Veterans Affairs National Acquisition Center, the expenditures for equipment, supplies, shipment and service fees have been tabulated by Projects, categories and costs. Tables are appended. Overall, during this past quarter most of the processed orders were delivered to Belarus and Ukraine and cleared from customs. The remaining non-delivered orders involve specialty productions which, although on track, have not reached the recipients as of this writing.

We anticipate a "steady state" procurement of consumables and replacements during the last quarter under the current Interagency Agreement. It should be noted that there appear to be enough funds for the UkrAm Thyroid project and only limited funds in BelAm Thyroid and UkrAm Leukemia projects. The leukemia activity should be adequately covered for the remaining period of the pilot phase; new funds must be allocated if the study should be extended to a full, long-term project. The Belarusian thyroid project is in need of additional funds, especially if the anticipated expansion to the Gomel area is to be undertaken. The REB staff is currently searching for additional funds.

PROCUREMENT BALANCE SHEET

	Supplies	Instruments	Computers	Fee	Shipment	Total	Balance
UkrAm Thyroid	36,835,14	92,623.26	51,948.92	11,212.34	5,465.09	198,084.75	206,025.25
BelAm Thyroid	40,523.16	56,356.42		5,971.57	2,646.71	105,497.86	75,902.14
UkrAm Leukemia	58,674.57	74,186.28	67,992.72	12,270,01	3,646,71	216,770.29	33,229.71

ATTACHMENT

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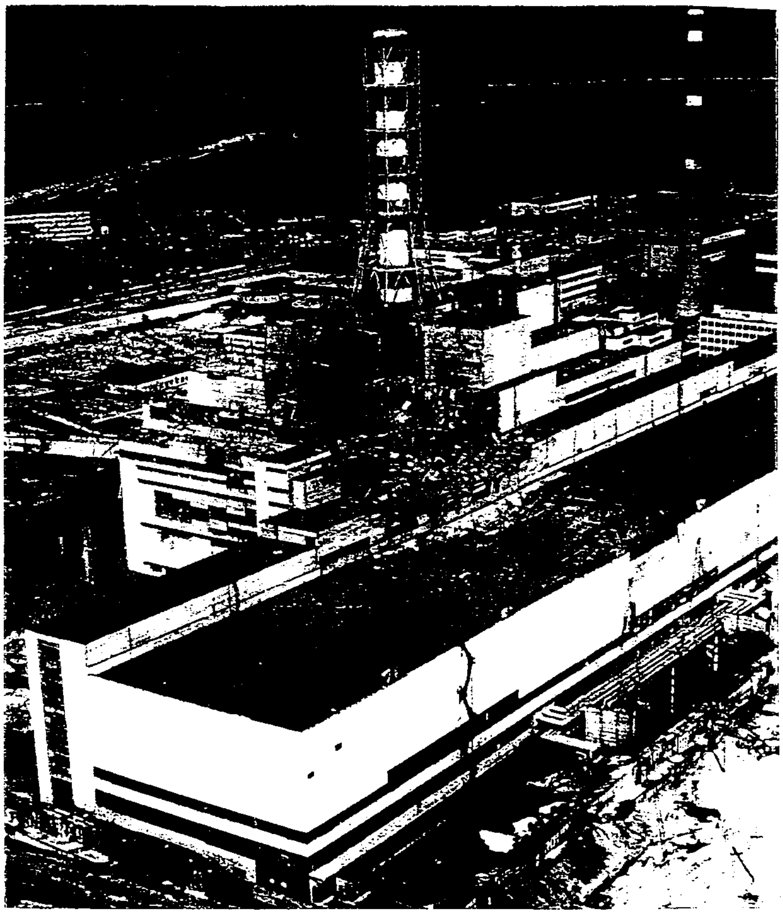
RADIATION EFFECTS BRANCH

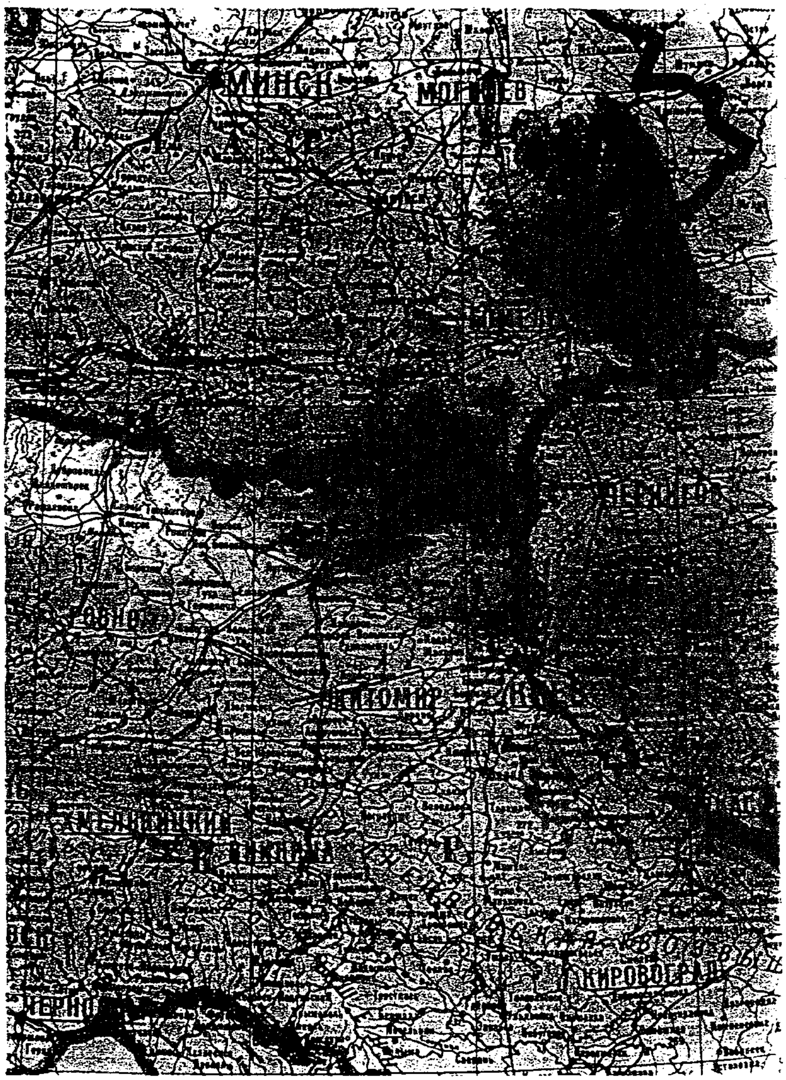
Source:

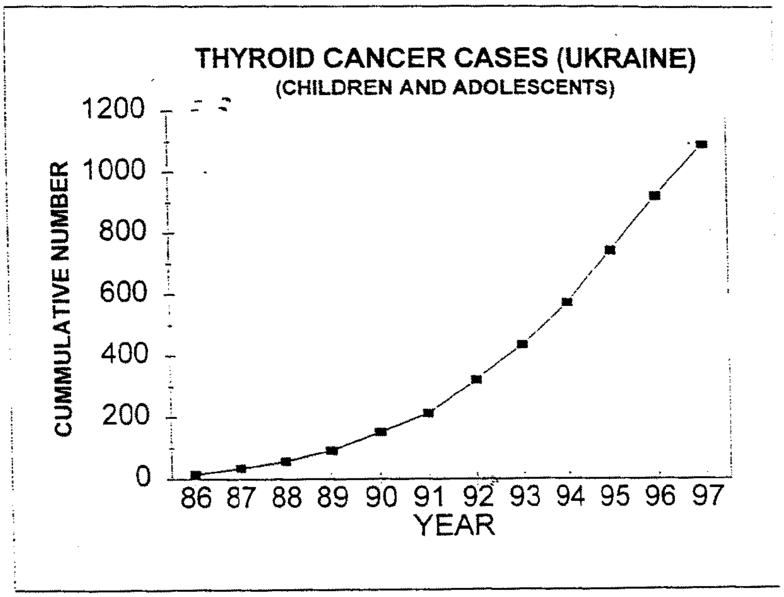
BRANCH CHIEF:	BRUCE W. WACHHOLZ
PROGRAM DIRECTORS:	RICHARD A. PELROY TBD
CHERNOBYL STUDIES:	IHOR J. MASNYK ANDRÉ C. BOUVILLE JACOB WECHSELBERGER (NICKOLAS LUCKYANOV)
SUPPORT STAFF:	MARY L. VELTHUIS RENEE C. CASTRO

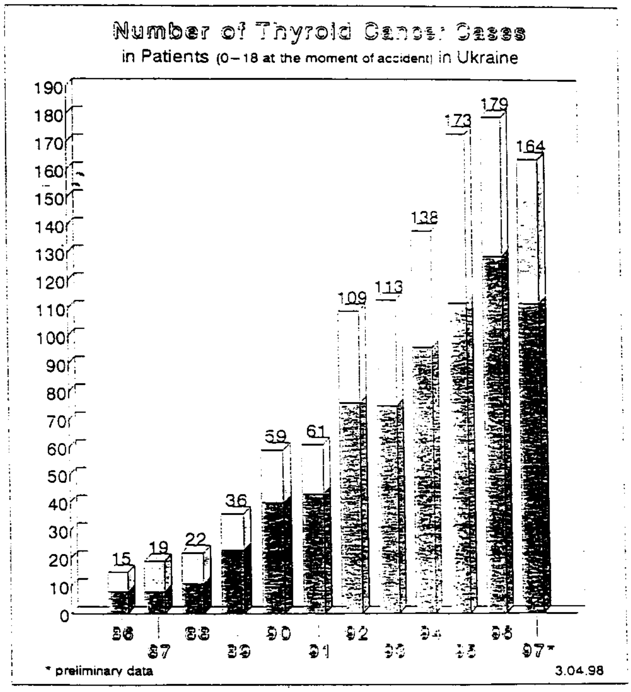
Briefing presented to NRC summer 1998 per Dr. Wachholz, NCI

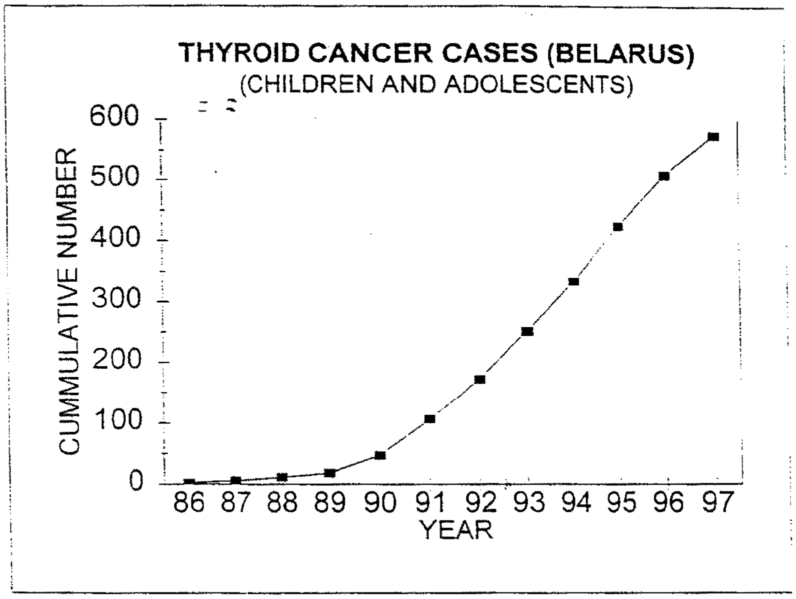


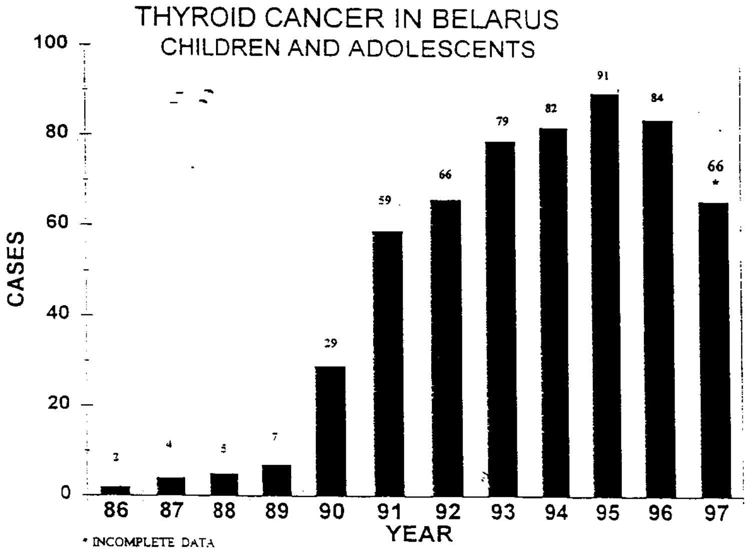
Доля повела у Чорнобиль „ліквідаторів“ різними шляхами. Одні потрапили сюди за покликом душі, інших привели професійні обов'язки або повістка військкомату. Микола Степанович Степаненко, колишній заступник голови Київського облвиконкому, приїхав на ЧАЕС 26 квітня одним з перших серед державних керівників. Йому дісталась найскладніша ділянка — займатись евакуацією, розселенням людей. Ось вже десять років ділить він гіркий чорнобильський окраєць разом з ліквідаторами й самоселами.


МИНСК
МОГИЛЕВ
ЧЕРНИГОВ
ЖИТОМИР
КИЕВ
ХМЕЛЬНИЦКИЙ
УКРАИНА
КИРОВОГРАД


THYROID CANCER CASES (UKRAINE)
(CHILDREN AND ADOLESCENTS)
CUMMULATIVE NUMBER
1200
1000
800
600
400
200
0
86 87 88 89 90 91 92 93 94 95 96 97
YEAR


Number of Thyroid Cancer Cases
in Patients (0–18 at the moment of accident) in Ukraine
190
180
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
15
19
22
36
59
61
109
113
138
173
179
164
86
87
88
89
90
91
92
93
94
95
96
97*
* preliminary data
3.04.98


THYROID CANCER CASES (BELARUS)
(CHILDREN AND ADOLESCENTS)
CUMMULATIVE NUMBER
600
500
400
300
200
100
0
86
87
88
89
90
91
92
93
94
95
96
97
YEAR


THYROID CANCER IN BELARUS
CHILDREN AND ADOLESCENTS
CASES
100
80
60
40
20
0
2
4
5
7
29
59
66
79
82
91
84
66 *
86
87
88
89
90
91
92
93
94
95
96
97
YEAR
* INCOMPLETE DATA

THYROID STUDIES

OBJECTIVES

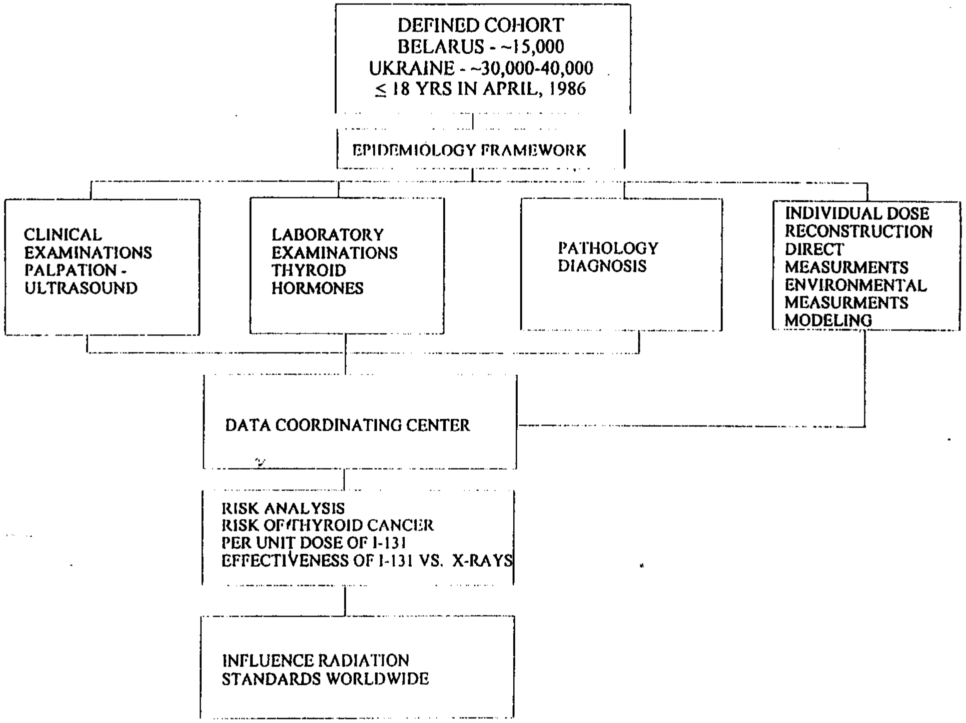
- RISK ESTIMATES FOR
  - CANCER
  - NODULES
  - HYPOTHYROIDISM

- RISK ESTIMATES AS A FUNCTION OF
  - DOSE
  - AGE AT TIME OF EXPOSURE
  - SEX

- COMPARE CARCINOGENIC POTENTIAL OF I-131 WITH THAT OF X-RAY AND GAMMA RADIATION

PURPOSE

- RADIATION PROTECTION GUIDELINES
- RISK ESTIMATION
- RETROSPECTIVE EVALUATION


DEFINED COHORT
BELARUS - ~15,000
UKRAINE - ~30,000-40,000
≤ 18 YRS IN APRIL, 1986
EPIDEMIOLOGY FRAMEWORK
CLINICAL EXAMINATIONS PALPATION - ULTRASOUND
LABORATORY EXAMINATIONS THYROID HORMONES
PATHOLOGY DIAGNOSIS
INDIVIDUAL DOSE RECONSTRUCTION DIRECT MEASURMENTS ENVIRONMENTAL MEASURMENTS MODELING
DATA COORDINATING CENTER
RISK ANALYSIS
RISK OF THYROID CANCER PER UNIT DOSE OF I-131
EFFECTIVENESS OF I-131 VS. X-RAYS
INFLUENCE RADIATION STANDARDS WORLDWIDE

CHERNOBYL PROGRAM
THYROID STUDIES

CASE-CONTROL STUDY (1992)
- BELARUS — 119 CASES OF CHILDREN WITH THYROID CANCER

COHORT STUDIES
- BELARUS — ~15,000 CHILDREN
- UKRAINE — ~30,000-40,000 CHILDREN
- CRITERIA FOR INCLUSION
    - AGE AT THE TIME OF THE ACCIDENT
    - RADIOACTIVITY OF THYROID MONITORED
    - GEOGRAPHIC LOCATION
- RISK ESTIMATES FOR CANCER, NODULES AND HYPOTHYROIDISM
    - DOSE
    - AGE AT TIME OF EXPOSURE
    - SEX
- COMPARE EFFECTIVENESS OF I-131 WITH THAT OF X-RAY AND GAMMA RADIATION

CHERNOBYL PROGRAM
THYROID STUDIES

DOSIMETRY

- THYROID MEASUREMENTS
  - RECALIBRATE AND STANDARDIZE INSTRUMENTS
    - BELARUS
      - RUSSIA
    - UKRAINE

- ENVIRONMENTAL MEASUREMENTS
  - AREA EXPOSURES/DOSES
  - DATA BASE
    - UKRAINE
    - BELARUS (NCI, EPA)

- PERSONAL QUESTIONNAIRES
  - RESIDENTIAL/DIETARY HISTORY
  - HEALTH/FAMILY HISTORY

CHERNOBYL PROGRAM
THYROID STUDIES

CLINICAL (ANNUAL/BIENNIAL)

- PHYSICAL
  - PALPATION
  - ULTRASOUND

- LABORATORY

- FNA (AS INDICATED)

- PATHOLOGY
  - INTERNATIONAL REVIEW

CHERNOBYL PROGRAM
THYROID STUDIES

OTHER

- BINATIONAL REVIEW GROUPS

- TISSUE REPOSITORIES
  - BELARUS, RUSSIA, UKRAINE
  - NCI, EC, JAPAN

LEUKEMIA STUDIES

OBJECTIVES

- DOSE -RESPONSE
  - LOW DOSE REGION
  - MODERATE DOSE REGION
- INFLUENCE OF DOSE-RATE
- TIME-RESPONSE
- EVALUATE AS INDICATOR OF
  - EXCESS SOLID TUMORS
  - EXCESS MORTALITY

CHERNOBYL PROGRAM
LEUKEMIA STUDIES

- PHASE I — 18 MONTHS
    - SAMPLING — SOURCES OF INFORMATION
        - CLEAN-UP WORKERS
        - REGISTRIES
    - DOSIMETRY
        - PHYSICAL
        - BIOLOGICAL
    - LEUKEMIA
        - ASCERTAINMENT (1986-199~~2~~6)
        - DIAGNOSTIC REVIEW/TERMINOLOGY
    - OTHER
- PHASE II

CHERNOBYL PROGRAM
BACKGROUND

1986: CHERNOBYL NUCLEAR POWER PLANT ACCIDENT
1987: PRESIDENTS REAGAN AND GORBACHEV
1988: JOINT COORDINATING COMMITTEE FOR CIVILIAN NUCLEAR REACTOR SAFETY
1989: DOE — HEALTH AND ENVIRONMENT
1990: NCI — THYROID AND LEUKEMIA STUDIES
1991-1996: DISSOLUTION OF USSR
IDENTIFICATION OF ORGANIZATIONS/INDIVIDUALS
DEVELOPMENT OF THREE RESEARCH PROTOCOLS
    PEER REVIEW
    IRB
FINANCIAL SUPPORT: NCI, DOE, NRC
1996: NCI-DOE INTERAGENCY AGREEMENT
FUNDING AGREEMENTS (UKRAINE AND BELARUS)
1996-1998: EQUIPMENT AND SUPPLIES
IMPLEMENTATION

STATUS

BELARUS

- DEVELOP EPIDEMIOLOGICAL REQUIREMENTS
- 2000 COHORT MEMBERS EXAMINED
  - 30 THYROID CANCERS
- SEARCHING FOR THOUSANDS OF ADDRESSES
- DATA COORDINATING CENTER FUNCTIONAL
- ESSENTIALLY ALL EQUIPMENT DELIVERED
- ONGOING NEED FOR SUPPLIES
- EXPECT AN ADDITIONAL 5,000 COHORT MEMBERS IN NEXT YEAR
- NEED TO ESTABLISH DIAGNOSTIC FACILITY IN GOMEL
  - POSSIBLY ALSO IN BREST
- NEED TO ESTABLISH/EQUIP MOBILE TEAM
- DOSE RECONSTRUCTION EFFORTS UNDERWAY

UKRAINE - THYROID STUDY

- DETERMINE EPIDEMIOLOGICAL REQUIREMENTS
- EXAMINATION OF COHORT MEMBERS BEGUN
    - SEVERAL HUNDRED AT PRESENT
    - EXPECT ~10,000 WITHIN A YEAR (ADDRESSES BEING SOUGHT)
- CONSIDERABLE EQUIPMENT/SUPPLIES TO BE DELIVERED
- DATA COORDINATING CENTER BECOMING FUNCTIONAL
- NEED FOR MOBILE DIAGNOSTIC LABORATORY (IES)
- DOSE RECONSTRUCTION EFFORTS UNDERWAY

UKRAINE - LEUKEMIA STUDY (PHASE I)

- DEVELOP DOSE RECONSTRUCTION TECHNIQUES
    - EPR TECHNIQUE
    - FISH TECHNIQUE
    - LOCATION/TIME/MOTION RECALL
- ASSESS MEDICAL RECORDS IN OBLASTS/RAIONS
- DEVELOP STANDARDIZED DIAGNOSTIC CRITERIA
- DEVELOP EPIDEMIOLOGY FRAMEWORK

MINISTRIES OF HEALTH
(1990-1998)
CHALLENGES

BELARUS	UKRAINE
3 MINISTERS OF HEALTH	5 MINISTERS OF HEALTH
3 DIRECTORS OF INSTITUTE OF RADIATION MEDICINE	CUSTOM DUTIES/TAXES
NEED TO OBTAIN APPROVAL OF PRESIDENT'S COUNCIL OF MINISTERS	NEW AGENCY FOR RECONSTRUCTION AND DEVELOPMENT
CUSTOM DUTIES/TAXES	IMPOSITION OF 60% TAXES

FINANCIAL SUPPORT
(PROGRAMMATIC - ESTIMATED)

	FY 1998	FY 1999
DOE	$ 800	$ 800
NCI (MATCHING FUNDS)	800	800
	$ 1,600	$ 1,600
SUPPORT CONTRACT	$ 1,200	$ 1, 274
LOCAL ASSISTANCE	290	394
OPERATIONS (STAFF, CONSULTANTS, OTHER	240	300
(INCLUDING TRAVEL)	$ 1,730	$ 1,968
SHORTFALL	$ 130	$ 168

(EQUIPMENT AND SUPPLIES)

NRC ($1,000 TO DOE IN FY 1994)	$ 0	$ 235 (REQUESTED)

($584 TO NCI IN FY 1997)
(IPSN - $250 TO NCI IN FY 1997)

EQUIPMENT AND SUPPLIES
(ESTIMATED AMOUNTS)

PROJECT	1999			2000		
	FUNDS AVAILABLE	PROJECTED EXPENSES	AMOUNT NEEDED	FUNDS AVAILABLE	PROJECTED EXPENSES	AMOUNT NEEDED
BELARUS						
THYROID STUDY	70,000	255,000	185,000	--	100,000	100,000
UKRAINE						
THYROID STUDY	196,000	246,000	50,000	--	210,000	210,000
LEUKEMIA STUDY	33,000	33,000	--			
PHASE I						
PHASE II						
				--	240,000- 290,000	240,000- 290,000

ATTACHMENT

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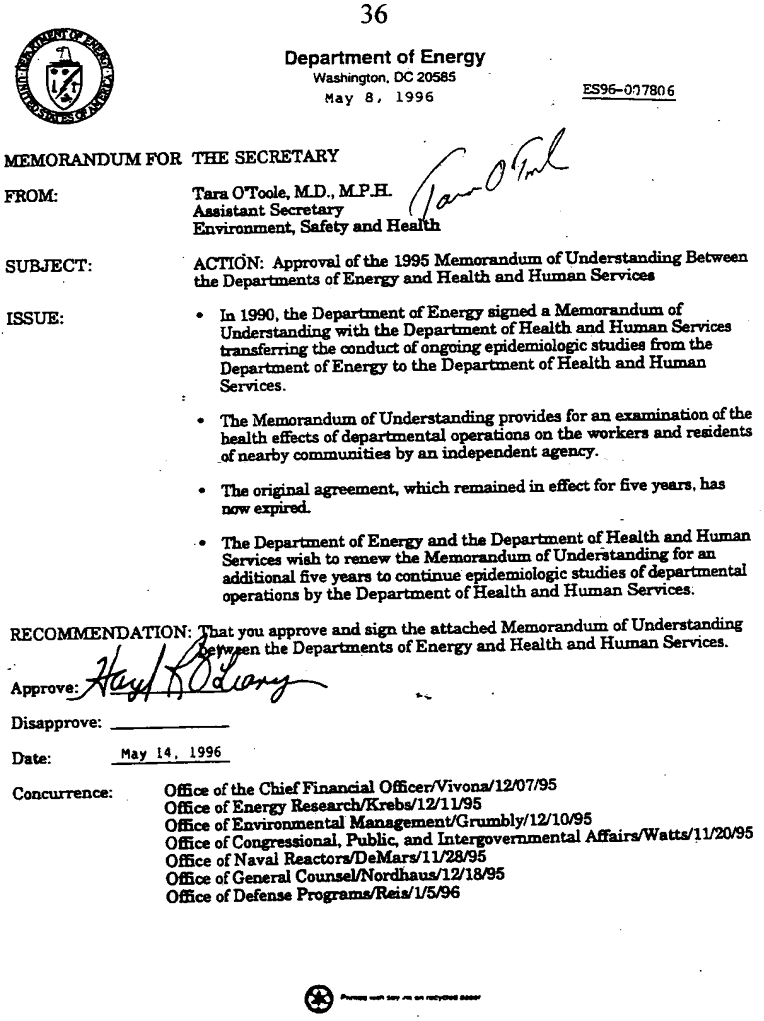

Department of Energy
Washington, DC 20585
May 8, 1996

ES96-007806

MEMORANDUM FOR THE SECRETARY

FROM: Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

Tara O'Toole

SUBJECT: ACTION: Approval of the 1995 Memorandum of Understanding Between the Departments of Energy and Health and Human Services

ISSUE:

- In 1990, the Department of Energy signed a Memorandum of Understanding with the Department of Health and Human Services transferring the conduct of ongoing epidemiologic studies from the Department of Energy to the Department of Health and Human Services.
- The Memorandum of Understanding provides for an examination of the health effects of departmental operations on the workers and residents of nearby communities by an independent agency.
- The original agreement, which remained in effect for five years, has now expired.
- The Department of Energy and the Department of Health and Human Services wish to renew the Memorandum of Understanding for an additional five years to continue epidemiologic studies of departmental operations by the Department of Health and Human Services.

RECOMMENDATION: That you approve and sign the attached Memorandum of Understanding between the Departments of Energy and Health and Human Services.

Approve: Hazel R O'Leary

Disapprove: ____________

Date: May 14, 1996

Concurrence:
Office of the Chief Financial Officer/Vivona/12/07/95
Office of Energy Research/Krebs/12/11/95
Office of Environmental Management/Grumbly/12/10/95
Office of Congressional, Public, and Intergovernmental Affairs/Watts/11/20/95
Office of Naval Reactors/DeMars/11/28/95
Office of General Counsel/Nordhaus/12/18/95
Office of Defense Programs/Reis/1/5/96

MEMORANDUM OF UNDERSTANDING
BETWEEN
DEPARTMENT OF ENERGY
AND
DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Background

In 1990, the Department of Energy and the Department of Health and Human Services entered into a five-year Memorandum of Understanding for the management and conduct of energy-related analytic epidemiologic studies relevant to Department of Energy operations. The Memorandum of Understanding also specified that the Department of Energy would conduct descriptive epidemiologic studies. The 1990 Memorandum of Understanding resulted in the transfer of a number of ongoing occupational epidemiologic and environmental dose reconstruction studies to the Department of Health and Human Services.

Since that time, the Department of Energy and the Department of Health and Human Services have coordinated their efforts in studying the potential health effects resulting from nuclear weapons production activities. Occupational studies transferred to the Department of Health and Human Services have now been completed and new studies are underway. Dose reconstruction projects that were transferred are still underway, and other environmental studies have been initiated. A new phase of this agreement has begun with the Department of Health and Human Services, which is conducting a program of independent, occupational and environmental research studies with funding from the Department of Energy. The Department of Energy has retained responsibilities for other health-related activities, such as health surveillance of current and former workers and other Department of Energy programs designed to ensure the health and safety of Department of Energy workers and community residents. The Department of Energy and the Department of Health and Human Services will make every effort to ensure that activities conducted under this Memorandum of Understanding and those conducted through other mechanisms are coordinated, non-duplicative, and supportive of a comprehensive research program.

II. Purpose

This Memorandum of Understanding replaces the 1990 Memorandum of Understanding and sets forth the guidelines for continuing the coordination between the Department of Energy and the Department of Health and Human Services for the energy-related health research program being conducted by the Department of Health and Human Services for the Department of Energy. The research under this Memorandum of Understanding focuses on the examination of health effects that may have resulted from past or current Department of Energy operations, including development and production of nuclear weapons and materials, environmental management, and other nuclear energy-related research and development activities. The Department of Energy and the Department of

Health and Human Services through the Centers for Disease Control and Prevention may mutually agree in the future to extend health research to potential hazards resulting from non-nuclear energy production and use.

The Office of Environment, Safety and Health, within the Department of Energy, is responsible for the coordination of activities conducted under this Memorandum of Understanding. Within the Department of Health and Human Services, the Centers for Disease Control and Prevention is the agency responsible for conducting this nuclear energy-related health research. Two Centers for Disease Control and Prevention components are involved in this effort. The National Center for Environmental Health conducts epidemiologic research in the community setting; the National Institute for Occupational Safety and Health conducts occupational health studies.

This Memorandum of Understanding sets forth the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of research studies of the following populations: workers at the Department of Energy facilities; residents of communities near Department of Energy facilities; and other persons potentially exposed to radiation and other hazards relevant to nuclear weapons production and research.

Priority will be given to those research areas that directly relate to assessing the health impacts of activities in and around Department of Energy facilities. This agreement is not meant to affect other Memoranda of Understanding and Interagency Agreements between the Department of Energy and the Department of Health and Human Services or to preclude the Department of Energy and the Department of Health and Human Services from entering into Memoranda of Understanding and Interagency Agreements for other purposes.

III. Authorities

A. The Department of Health and Human Services/Public Health Service has legislative authority under section 301(a) of the Public Health Service Act (42 U.S.C. section 241) and under the Occupational Safety and Health Act (29 U.S.C. section 669(a)) to conduct research into the health effects of a broad range of environmental and occupational hazards and to cooperate with other appropriate authorities in the conduct of such research. The National Institute for Occupational Safety and Health has authority to conduct health hazard evaluations (part 85) and other workplace investigations (part 85a) pursuant to 42 C.F.R. parts 85 and 85a. This statutory authority does not presently apply to the Department of Energy. A current Department of Energy initiative to accept the regulatory authority of the Occupational Safety and Health Administration may result in the future inclusion of the Department of Energy under 42 C.F.R. parts 85 and 85a.

B. Pursuant to the Atomic Energy Act of 1954, section 31a (42 U.S.C. 2051a), and the Energy Reorganization Act of 1974, section 103(3) (42 U.S.C. 5813(3)), the Department of Energy is authorized to conduct, and to make arrangements for the conduct of, research activities relating to the protection of health and the promotion of safety related to its research and production activities and the development of energy sources and utilization technologies. To achieve these objectives, the Department of Energy may, in addition to its own resources and programs, use the technical and management capabilities of other executive agencies having facilities, personnel, or other resources that can assist in carrying out such responsibilities, Atomic Energy Act, section 161 (42 U.S.C. 2201), Energy Reorganization Act, section 104(i) (42 U.S.C. 5814(i)), and the Economy Act of 1932, as amended (31 U.S.C. 1535).

IV. Department of Energy Responsibilities

A. Access to Department of Energy Data Sources

Consistent with applicable law, including but not limited to the Privacy Act (5 U.S.C. 552a), Department of Energy regulations (such as 10 C.F.R. 745, 10 C.F.R. 1008, and 10 C.F.R. 1016-1017), and contracts and agreements between the Department of Energy and its contractors, the Department of Energy will provide the Department of Health and Human Services access to necessary data and other documents for the management and conduct of health studies and programs, as described in this Memorandum of Understanding, including data on occupational and community exposure and environmental releases. The Department of Energy and the Department of Health and Human Services are jointly preparing a "Handbook for the Centers for Disease Control and Prevention Access to Department of Energy Sites and Records in Performance of Health Research and Related Studies" that shall be used as a reference guide to facilitate access to Department of Energy sites by Department of Health and Human Services investigators. The Department of Energy and its contractors shall continue to maintain documents, records, record systems, and other information sources for the conduct of epidemiologic research. Although the Department of Health and Human Services will be provided with access to relevant information and will possess copies of such data for use in its research, the data will remain the property of the Department of Energy.

In 1995, the Department of Energy amended various Privacy Act systems of records to establish "routine uses" for Department of Health and Human Services-sponsored health studies. To the extent that existing regulations, Privacy Act systems of records, or contracts and agreements between the Department of Energy and its own contractors continue to inhibit disclosure of data held by the Department of Energy or its contractors to the Department of Health and Human Services, or subsequent use and disclosure by the Department of Health and Human Services under section V.H., below, the Department of Energy will seek to revise as soon as practicable such regulations, systems of records, and contracts and agreements, as necessary and appropriate, so as to permit such disclosure and use. The Department of Energy will also make every effort to ensure that all future agreements or contracts entered into by the Department of Energy governing data that may be relevant for studies to be conducted by the Department of Health and Human Services under this Memorandum of Understanding will permit use and disclosure of that data to the Department of Health and Human Services and its subsequent use under section V.H., below.

To the extent consistent with the Federal Privacy Act, Department of Energy regulations and contracts, and agreements between the Department of Energy and its contractors, the Department of Energy will allow the Department of Health and Human Services personnel, contractors, grantees, and cooperative agreement holders with appropriate security clearances, as necessary, access to all Department of Energy and Department of Energy-owned, contractor-operated facilities for the purpose of independently reviewing or collecting any health, medical, personnel, occupational exposure, or environmental information or samples that the Department of Health and Human Services determines are necessary for conducting epidemiologic research under this Memorandum of Understanding.

B. Classification of Documents and Security Clearances

The Department of Energy and its contractors will continue to perform classification reviews of documents and data necessary for the Department of Health and Human Services to conduct the studies and programs described herein. Department of Health and Human Services personnel with appropriate security clearances will, in the course of conducting their epidemiologic studies, review classified documents and data to determine those that will be needed to conduct epidemiologic research. The Department of Energy will, wherever possible, declassify or downgrade these documents and data for Department of Health and Human Services use.

The Department of Energy will expedite appropriate security clearances for designated Department of Health and Human Services personnel or its contractors and grantees and, in accordance with Executive Order 12968, will accept, when possible, current Department of Health and Human Services security clearances, so that Department of Health and Human Services personnel with the appropriate level of clearance may examine classified documents and enter Department of Energy and Department of Energy-owned, contractor-operated facilities.

C. Department of Energy Representation on Department of Health and Human Services' Advisory Committee on Energy-Related Epidemiologic Research

The Department of Energy will participate in the development of the Department of Health and Human Services' research agenda by having a Department of Energy representative serve as a non-voting member of the Department of Health and Human

Services' Advisory Committee on Energy-Related Epidemiologic Research that will provide advice to the Department of Health and Human Services in setting its research agenda and in conducting its research program. The Department of Energy will provide input to the committee on projects proposed under the Memorandum of Understanding and submit to the committee any additional proposals for projects that the Department of Energy wishes to see conducted under this Memorandum of Understanding.

D. Office of Management and Budget/Congressional Submissions

For fiscal years 1997-2000, the Department of Energy will forward to the Office of Management and Budget, for inclusion in the President's budget, a request for resources necessary to support the approved research agenda for that fiscal year under this Memorandum of Understanding within funding constraints. For each fiscal year, Department of Energy and Department of Health and Human Services staff will meet to determine the amount of funding required for support of this program. The Department of Health and Human Services will provide the Department of Energy with this information with sufficient lead time for the budget request process. The Department of Energy will notify the Department of Health and Human Services of the amount requested and, at the earliest opportunity, notify the Department of Health and Human Services of the amount to be transferred.

E. Official Point-of-Contact

The Department of Energy designates the following individual as the official point-of-contact for this Memorandum of Understanding:

Name:	Tara O'Toole, M.D., M.P.H. (or successor)
Title:	Assistant Secretary for Environment, Safety and Health
Address:	U.S. Department of Energy, Washington, DC 20585
Telephone:	(202) 586-6151; Facsimile: (202) 586-0956

F. Naval Nuclear Propulsion Program

Where applicable, the Director, Naval Nuclear Propulsion Program, will establish the necessary provisions with the Department of Health and Human Services for epidemiologic studies undertaken by the Department of Health and Human Services at Naval Nuclear Propulsion facilities and activities.

V. The Department of Health and Human Services Responsibilities

A. Department of Health and Human Services Advisory Committee on Energy-Related Epidemiologic Research

The Department of Health and Human Services will continue to support its Advisory Committee on Energy-Related Epidemiologic Research. This committee is chartered to provide advice to the Secretary of the Department of Health and Human Services in recommending research approaches and a research agenda and in conducting the research program as outlined in this Memorandum of Understanding. Members of the advisory committee will consist of representatives selected by the Secretary of the Department of Health and Human Services from non-Federal employees and will include research scientists, public health officials, representatives of public interest groups, and representatives of affected parties (e.g., Native American Tribes, workers, community residents). Both the Department of Health and Human Services and the Department of Energy will have non-voting members on this committee.

The Department of Health and Human Services Advisory Committee on Energy-Related Epidemiologic Research will provide advice and recommendations to the Department of Health and Human Services on establishing a research agenda for studies to be conducted under this Memorandum of Understanding. The Department of Health and Human Services Advisory Committee on Energy-Related Epidemiologic Research also will consider information and proposals from other agencies and organizations. A mechanism will be established to ensure that the Advisory Committee on Energy-Related Epidemiologic Research considers the concerns of community residents, Native Americans, workers, and other affected parties through the recommendations of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry's established site-specific citizens' health effects subcommittees.

B. Establishing the Research Agenda

The Department of Health and Human Services will propose a research agenda to the Advisory Committee on Energy-Related Epidemiologic Research for future fiscal years. The Department of Energy will review the proposed agenda and present its comments to the Advisory Committee on Energy-Related Epidemiologic Research, including any additional research the Department of Energy wishes to have conducted under this Memorandum of Understanding. Comments will include an assessment of the priority to be given to each research project based on the Department of Energy's health research needs.

The Department of Health and Human Services will then establish the final research agenda based on the recommendations of the Advisory Committee and will incorporate the agenda into a research plan, including timelines, for the conduct of energy-related health research under this Memorandum of Understanding, and this plan will be provided to the Department of Energy for review and comment. The authority to finalize this research plan resides with the Secretary of the Department of Health and Human Services.

The plan will be revised each fiscal year to incorporate changes in the research agenda and to reflect changes in available resources in accordance with procedures described above.

The Department of Health and Human Services will have responsibility for the conduct of a program of health studies, historical dose reconstruction, and exposure assessment studies. When the need arises, the Department of Health and Human Services and the Department of Energy may conduct energy-related health studies not specified in the research plan. Funds for such research must be in addition to funds allocated for the research outlined in the research plan, unless the use of such funds is agreeable to both parties.

C. Conducting Research Activities

The Department of Health and Human Services will have sole responsibility for the design, conduct, analysis, and scientific interpretation of studies and programs conducted by the Department of Health and Human Services, its contractors, grantees, or cooperative agreement holders under this Memorandum of Understanding.

The Department of Health and Human Services will decide which studies will be performed intramurally and which will move to open competition for all extramural research. The Department of Health and Human Services will develop a schedule for determining when continuing programs will be competed. The Department of Health and Human Services has the discretion to begin new intramural or extramural research consistent with the approved research agenda and resource availability.

D. Procedures for Conducting Research

The Department of Health and Human Services will employ established procedures for awarding research grants and contracts pursuant to Departmental regulations at 45 C.F.R. part 74. These mechanisms include open competition, peer review, a competitive system for project renewals, and quality assurance for research in progress. The Department of Energy National Laboratories will be eligible to compete in this process along with other applicants to the extent permitted by law and Department of Energy policies.

Intramural and extramural research will be conducted in accordance with established mechanisms for assuring scientific excellence through the peer-review process.

Representatives of populations being studied shall be included in review panels for studies conducted under this Memorandum of Understanding. These panels will allow for public, worker, and Native American comment on the design and conduct of all studies. Results of the studies will be communicated based on a joint communication plan being developed by the Department of Health and Human Services and the Department of Energy.

E. Protection of Human Subjects

1. Both the Department of Energy and the Department of Health and Human Services are committed to the protection of members of the public and the workforce from any risks that may be encountered in conducting research under this Memorandum of Understanding. To assure that citizens and workers are duly protected, specific requirements, described in Section V below, for monitoring the conduct of this research have been formulated that must be followed by the agencies.

   The Department of Health and Human Services shall provide evidence satisfactory to the Department of Energy that each institution conducting or managing research under this Memorandum of Understanding has provided the Department of Health and Human Services with written assurance that such institution(s) will comply with the requirements of 45 C.F.R. part 46, Protection of Human Subjects, and that such assurance, appropriate for the research in question, is on file with the National Institutes of Health's Office of Protection from Research Risks and is approved for Federal-wide use by that office.

2. The Institutional Review Board approval or determination of exempt status for the project protocol or plan must be received before data collection begins. The following project information shall be provided by the Department of Health and Human Services to the Department of Energy and to the Department of Energy's management and operating contractor for the Department of Energy site/facility involved:

   (a) A membership list of the Institutional Review Board of record under which the project proceeds;

   (b) A copy of the Institutional Review Board's approval for each project, including evidence of any conditions imposed on or any unique circumstances of the research to be conducted; and

   (c) A completed copy of the Department of Energy Human Subjects Research Project Database forms for each project that has been approved by the Institutional Review Board's review. Projects deemed exempt by the Institutional Review Board do not need to fulfill this requirement.

3. A separate document is being developed which will outline the roles and responsibilities of Department of Energy institutional review boards for studies conducted under this Memorandum of Understanding. The document is being developed with assistance from the Office of Protection from Research Risks within the Department of Health and Human Services and guidance will be provided separately.

F. Department of Health and Human Services Data Sources

The Department of Health and Human Services will be responsible for the management of all data collected by Department of Health and Human Services employees, its contractors, grantees, and cooperative agreement holders, including data obtained from the Department of Energy and its contractors. Consistent with the Privacy Act, Department of Energy regulations, contracts and agreements with Department of Energy contractors, and section V.H., below, Department of Health and Human Services personnel, contractors, grantees, and cooperative agreement holders with appropriate security clearances (when required to review classified information) will have access to all Department of Energy and Department of Energy-owned, contractor-operated facilities for the purpose of independently reviewing or collecting health, medical, personnel, occupational exposure, or environmental information data or samples that the Department of Health and Human Services determines are necessary for conducting the epidemiologic research. The Department of Health and Human Services shall ensure that any reviews of record systems containing personally identified data, undertaken as a basis for study project/protocol development, are reasonably limited in scope and duration and that information collected is directed to preparation of forms and procedures for use in such project/protocol plan(s).

G. Classification of Documents and Security Clearances

Department of Health and Human Services personnel with appropriate security clearances will review documents and data necessary for the Department of Health and Human Services to conduct the studies and programs described herein. The Department of Health and Human Services will expedite completion of all necessary paperwork for appropriate security clearances to facilitate the Department of Energy's clearance determinations for Department of Health and Human Services personnel, so that they may examine classified documents and enter Department of Energy and Department of Energy-owned, contractor-operated facilities.

H. Use and Disclosure of Information

Establishment of Privacy Act Systems

The Department of Health and Human Services will maintain the necessary Privacy Act System of Records for information provided to the Department of Health and

Human Services by the Department of Energy (or will include such information in Department of Health and Human Services' existing Privacy Act systems). Before integrating Department of Energy data into a Department of Health and Human Services system of records, the Department of Health and Human Services will consult the Department of Energy about provisions of the system notice, including the routine uses, applicable to Department of Energy data in the system. Before establishing a new or modifying an existing system of records for Department of Energy data, the Department of Health and Human Services will consult the Department of Energy Headquarters Privacy Act officer about the provisions of the system notice, as required by the Privacy Act, including the routine uses, applicable to Department of Energy data in the Privacy Act system.

Disclosure of Information to the Public Generally

Information provided to the Department of Health and Human Services under this agreement may be made available by the Department of Health and Human Services in response to requests under the Freedom of Information Act (5 U.S.C. section 552) and implementing regulations, 45 C.F.R. part 5. In making decisions about disclosure, the Department of Health and Human Services will consult the Department of Energy about any personally identifying information provided by the Department of Energy or any other information identified in advance by the Department of Energy as warranting such consultation.

Disclosure of Personally-Identifiable Information for Research Purposes

As provided under applicable laws, the Department of Health and Human Services will not use or disclose any personally identifiable information obtained from the Department of Energy or its contractors except for research purposes. The Department of Health and Human Services will not use information in identifiable form to make any determination about the rights, benefits, or privileges of any individual. The Department of Health and Human Services will use and disclose this information in accord with agreements under which the personally identifiable information was obtained by the Department of Energy or its contractors, provided this is consistent with applicable law. The Department of Health and Human Services may disclose this information outside of the Department of Health and Human Services for research purposes to persons or entities it deems qualified after consultation with the Department of Energy and in accord with the provisions for disclosure in the Department of Health and Human Services Privacy Act notices. The Department of Health and Human Services shall notify the Department of Energy of any efforts on the part of anyone to obtain or use personally identifiable information for purposes other than research conducted under this Memorandum of Understanding, e.g., subpoenas, and shall use and take appropriate steps to prevent improper disclosure. The Department of Health and Human Services will obtain any necessary approvals to allow disclosure of data held by the Department of Energy and assist the

Department of Energy, as necessary, in revising any Privacy Act systems, contracts, or agreements (as required by section IV.A., above) that preclude disclosure to the Department of Health and Human Services of data held by the Department of Energy or its contractors.

I. Release of Data from Completed Studies

The Department of Health and Human Services jointly with the Department of Energy will promptly disseminate results obtained through research covered by this Memorandum of Understanding to the populations being studied in accordance with the communication plan being developed jointly by the Department of Energy and the Department of Health and Human Services. Public access to data in the Department of Health and Human Services studies will be governed by applicable Federal laws, including the Freedom of Information Act (5 U.S.C. 552) and Department of Health and Human Services implementing regulations. After the Department of Health and Human Services studies have been completed, study data will be made available to the Comprehensive Epidemiologic Data Resource, without personal identifiers, subject to the provisions of sections V.G. and V.H., above. The data, with appropriate documentation, will be provided to the Comprehensive Epidemiologic Data Resource without personal identifiers no later than six months after the completion of the study, or at termination of a contract, grant, or cooperative agreement, whichever occurs first, subject to the provisions of sections V.G. and V.H., above. The Department of Energy will also solicit input from the Department of Health and Human Services on the Comprehensive Epidemiologic Data Resource's continuing development and expansion, including the selection of data to be included in this public-use data repository.

J. Reports to the Department of Energy

The Department of Health and Human Services will continue to provide complete fiscal and progress reports to the Department of Energy on a quarterly basis in a format that meets the Department of Energy's financial reporting needs.

K. Responsible Official

The Department of Health and Human Services designates the following individual as the official point-of-contact for this Memorandum of Understanding:

Name:	David Satcher, M.D., Ph.D. (or successor)
Title:	Director, Centers for Disease Control and Prevention
Address:	1600 Clifton Road, N.E., Atlanta, GA 30333
Telephone:	(404) 639-7000; Facsimile: (404) 639-7111

VI. Resources

The Department of Energy will provide and transfer resources to the Department of Health and Human Services for the purpose of conducting energy-related health research studies for this Memorandum of Understanding. The funding and full-time equivalent employment levels will be determined annually by agreement between designated agency official points-of-contact for this Memorandum of Understanding (for the Department of Energy, see section IV.E.; for the Department of Health and Human Services, see section V.K.). Upon mutual agreement, resource levels may be amended at any time during the fiscal year.

The details of the levels of support to be furnished by the Department of Energy to the Department of Health and Human Services will be developed annually through an interagency agreement. The Department of Health and Human Services will provide to the Department of Energy a description and justification for funding and full-time equivalent resource requirements for submission to the Office of Management and Budget and Congress for the studies and programs described under this Memorandum of Understanding. These submissions will be provided by the Department of Health and Human Services to the Department of Energy in a timeframe agreed upon that is consistent with the Department of Energy's budget cycle.

The Department of Health and Human Services will not accept responsibility for specific studies or undertake new programs unless the mutually agreed level of resources is sufficient to achieve the intended goals and objectives. If equipment is procured in order to provide service under this Memorandum of Understanding, the Department of Health and Human Services will retain title to the equipment.

Any requirement for payment or obligation of funds by the Department of Energy established by the terms of this agreement shall be subject to the availability of appropriated funds.

For the purpose of studies conducted by the Department of Health and Human Services or its contractors, grantees, and cooperative agreement holders, the Department of Health and Human Services will prepare the necessary information collection proposals for the Office of Management and Budget approval under the Paperwork Reduction Act. These proposals will be submitted by the Department of Health and Human Services to the Office of Management and Budget. In the event that the Office of Management and Budget fails to approve the information collection or allow adequate burden hours, the Department of Health and Human Services will be under no obligation to undertake or complete individual studies but will advise the Department of Energy and work with the Department of Energy to secure Office of Management and Budget approval, which may result in necessary modification of reporting requirements.

VII. Duration of Agreement

This agreement, effective when signed by both parties, shall initially remain in effect through fiscal year 2000, unless amended by mutual written consent of both parties. There is every intention to renew this agreement after five years.

VIII. Modification or Cancellation

This agreement, or any of its specific provisions, may be revised by signature approval of both parties signatory hereto, or their respective designees.

Cancellation of the agreement may be accomplished only at the expiration of 90-day advanced notification by either party.

DEPARTMENT OF ENERGY

By: Hazel R. O'Leary
Hazel O'Leary
Secretary

Date: May 14, 1996

DEPARTMENT OF HEALTH AND HUMAN SERVICES

By: ______________________
Donna Shalala
Secretary

Date: ______________

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 4

THE SOPHIE DAVIS SCHOOL
CITY UNIVERSITY OF NEW YORK MEDICAL SCHOOL
OF BIOMEDICAL EDUCATION

*Department of
Community Health
and Social Medicine*

H. Jack Geiger, M. D., M.Sci.Hyg.
Arthur C. Logan Professor of Community
Medicine Emeritus
e-mail jgeiger@igc.apc.org

September 23, 1998

Mr. Peter Tyler
Office of Senator Harkin
VIA FAX 202-224-1972

Dear Mr. Tyler:

As I indicated to you by telephone yesterday, I have just learned that there is a serious error of fact in the testimony sent by Dr. Rush and myself and submitted by Senator Harkin to be included in the record of the hearing by the Senate Permanent Investigations Subcommittee on September 16, 1998. I am writing to correct that error and to request the deletion of those sections of the testimony that contain or refer to it.

The error is in those sections of the testimony that state, or comment on, an allegation that the National Cancer Institute refused to share important information requested by the National Research Council/Institute of Medicine report review panel, and that the panel never received this information and did not comment on that fact in its final report. In fact, as the final report makes clear, the review panel did receive this information and it is described and discussed in considerable detail on pp. 62-64 of the final report. While I did not prepare this section of the testimony, as a signatory to the testimony I share responsibility for it. I regret this error and believe it is important, in the interests of fairness and accuracy, to set the hearing record straight.

I have gone through a copy of the submitted testimony in detail and believe that can be accomplished by a number of deletions, as follows:

1. Items 2, 3 and 4 on pp. 2-3 of the testimony should be deleted. This is the text beginning "In spite of a DHHS assertion..." in point 2, through "embarrassing NCI' in point 4. In the copy that I have, this material starts on marked line 12 of page 2 and ends with marked line 1 on page 3. (This will presumably also require renumbering of the subsequent points).

138TH STREET & CONVENT AVENUE AT CITY COLLEGE CAMPUS
NEW YORK, NEW YORK 10031 · TEL 212 650 6860 · FAX 212 650 7768

2. The heading "NCI Obstruction Without Effective NRC Response" should be deleted, as should the text that follows on pp. 6-8 of the testimony. This consists of 23 lines of text, beginning with "In an August 11 response..." And ending "NCI's behavior in their final report." In my copy of the testimony, this begins on line 14 of page 5 and continues through line 18 on page 6. The only material that should remain from this entire section, and appear as a separate paragraph without any heading, is the sentence that begins "We shall further document, below..." and ends "far too optimistic." This paragraph would now follow the concluding sentence of the originally preceding section, ending "legislation be be fulfilled" on line 12, page 5 of my copy of the testimony.

3. Finally, there are two minor corrections unrelated to the above. First, I believe the very last sentence of the section headed "Offer But Discourage..." should be deleted. This is the sentence beginning "The NRC panel chose not to seriously consider..." and ending "any recommendation for it." (It appears on page 16 of my copy). This is because the final report did include a recommendation to await the results of the Hanford Thyroid Disease Study before making a decision. Second, I have noticed one technical error that is easy to correct. In the third paragraph of the same section on "Offer But Discourage" there is a sentence that reads "Mainly it is that the vast majority of single nodules are benign adenomas, not cancers, etc. The word "single" should be deleted, so that the sentence would read "Mainly it is that the vast majority of nodules are benign adenomas," etc.

I apologize for any difficulties these deletions may entail, but it would be misleading and unfair to have the final hearing record contain a factual inaccuracy and thus seem to impugn the integrity of the report review panel, an issue very different from disagreements on science and policy. Please also bring this to the attention of Senator Harkin.

Please call me (at 212-650-6860 or 718-855-5503) of fax me (at 718-802-9141) if there are any questions about these corrections. I will also mail a copy of this faxed letter.

Sincerely,

H. Jack Geiger

H. Jack Geiger, M.D.

cc: Senator Susan M. Collins
Senator John Glenn
Dr. Peter Raven, NRC
Dr. Kenneth I. Shine, IOM

Testimony by Drs. David Rush and H. Jack Geiger

submitted to the Senate Permanent Investigations Subcommittee

Wednesday, September 16, 1998

concerning the National Research Council (NRC)/ Institute of Medicine (IOM) review of the congressionally mandated study by the National Cancer Institute (NCI) of the health impact of fallout from nuclear weapons testing at the Nevada Test Site.

Good morning. We believe that the NCI study, and its subsequent NRC/IOM review are seriously flawed, and that specific Congressional action is warranted in response.

My name is David Rush, MD, and this testimony has been written jointly by me and H. Jack Geiger, MD. Dr Geiger is Logan Professor Emeritus and former chair of Community Medicine at the City University of New York Medical School, and formerly chair of the departments of Preventive Medicine at Tufts University and at State University of New York at Stony Brook, and is a member of CDC's Advisory Committee on Energy Related Epidemiologic Research (ACERER). I am an epidemiologist and pediatrician, emeritus professor of Nutrition, Community Health and Pediatrics at Tufts University, and formerly a tenured member of the faculty of public health at Columbia University, and a professor and head of the Division of Pediatric and Perinatal Epidemiology at the Albert Einstein College of Medicine in New York City. I am past-president of the Society for Epidemiologic Research. I serve on the of the Department of Energy's Scientific Review Group for joint US-Russian studies on the effect of radiation on the health of those exposed by nuclear weapons production in the former Soviet Union under the aegis of the Joint Coordinating Committee for Radiation Effects Research. Dr Geiger and I were the principal authors of "Dead Reckoning", a review of the DOE's epidemiologic research on the health effects of exposure to ionizing radiation among the workers at its nuclear weapons production plants that was published by Physicians for Social Responsibility.

Our critique today falls under two main headings: the candor and objectivity of the report of the NRC panel, and the soundness of its recommendations for responding to the needs of those exposed to radioactive Iodine by nuclear weapons testing at the Nevada test site. We will first enumerate our points, and elaborate on them below. Our recommendations are at the end of our testimony.

1.) The NCI study falls far short of fulfilling the mandate of its enabling legislation, PL 97-414; The NRC review notes this omission, concurs with it in its summary[1], but does **not** concur with it in its text[2].

2.) In spite of a DHSS assertion that it was completely open with the public and cooperative with the NRC panel, there is internal evidence from an NRC draft report that the NCI refused to share important information requested by the NRC panel.

3.) Rather than demanding this withheld information from NCI, the NRC panel chose to expend, and we believe, waste, time and resources in an attempt to fill the gap caused by the NCI refusal.

4.) The final NRC report omits mention of this NCI refusal, described in the earlier draft. This omission does not correct data or clarify results, but certainly does serve to avoid embarrassing NCI.

5.) The discussion of screening in the NRC report is incomplete, and may be misleading, given the increasing incidence but decreasing mortality from thyroid cancer over the last decades, which is difficult to explain except as a benefit of improved treatment of thyroid cancer.

6.) The NRC recommendations for future research are incomplete and we believe, poorly prioritized; they do not adequately address the most central obstacles to creating an effective and coherent public health response to the iodine-131 (I-131) dispersion from nuclear weapons testing.

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[1] Exposure of the American people to Iodine-131 from Nevada Nuclear-Bomb Tests: Review of the National Cancer Institute Report and Public Health Implications, National Academy Press, 1998; ("The Review") page ES 8

[2] The Review. Page 137

7.) The NRC report has its own strong scientific biases, and is deeply uncritical of the work of the NCI, particularly the extraordinarily slow execution of the work and the five year gap between the essential completion of the work, and its release.

8) The NCI, and the NRC panel dealt only tangentially with the effects of fallout on thyroid diseases other than cancer. We believe this is a serious omission.

9.) Finally, and most importantly, neither the NRC report nor the NCI study effectively addresses these overriding facts: that the threat to the public health under study was government induced; that it was inflicted upon a loyal, and, at that time, trusting and unsuspecting populace; and that there is a history of hollow reassurance, cover-up and deception on the part of the agencies in question, primarily DOE and its predecessors, but also DHHS. This government responsibility urgently demands, we believe, the taking of several steps which we specify at the conclusion of our testimony.

GOVERNMENT RESPONSIBILITY, AND ITS ETHICAL CONSEQUENCES

There is much evidence that government scientists and top officials were aware of how widely fallout would be distributed from atmospheric weapons testing and that people exposed to radioactive fallout would incur added risks for cancer and other diseases. [Indeed, the government's sovereign immunity defense rests on the claim that, from the earliest days of the testing program, government officials were very much aware of the hazards when they exercised their "discretionary function" not to alert the public.[3]] The government, through the Federal Torts Compensation Act (FTCA), has stymied the ability of exposed and injured persons to seek redress for their injuries through the courts. Even if exposed persons can show the court that their injuries were caused by radiation from U.S. weapons testing or nuclear materials production activities, the sovereign immunity protections of the FTCA make it all but impossible for the courts to find against the government.

THE MANDATE OF P.L. 97-414

P.L. 97-414 became law on 4 January, 1983. Section 7(a) not only requires the secretary of Health and Human Services (HHS) to estimate the doses of I-131 received by the American people from nuclear weapons tests, but also requires that each individual's risk of developing thyroid cancer from this exposure be calculated. NCI did not make these estimates and calculations, and the NRC panel seconded their decision not to do so, in large part because of the extraordinarily inadequate monitoring of fallout during the years under study. However, there are experts who assert that it is possible to identify those subgroups at highest risk, in spite of limitations in the exposure data.

The central gap in NCI's work relates to section 7(b). This requires that HHS calculate the individual exposure and risk from all radionuclides spread by Nevada test site weapons testing for all radiation-induced cancer. We strongly disagree with DHHS's decision not to address these Congressional requirements, a decision with which the NRC panel concurred in its summary, with little or no explanation[4]. However, the text of the panel's report is far different, and broaches the issue of doing this research[5]. There is no evidence NCI sought Congressional approval for omitting this mandated research, and we believe that this omission is a grave one, and requires more than apology or explanation: it requires immediate correction. We also believe that the scientific evidence, as well as government culpability, demands that the intent of the original legislation be fulfilled.

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[3] In defending the government in Alice P. Broudy v United States, et al., U.S. District Court, C.D. CA, Civil No. 79-2626-LEW, November 1985, the U.S. Department of Justice stated that "government officials and scientists were aware of the hazards of radiation since the inception of the nuclear weapons program...specifically that fallout could cause cancer."

NCI OBSTRUCTION WITHOUT EFFECTIVE NRC RESPONSE

In an August 11 response to a letter sent to Secretary Shalala on July 9, 1998 by Susan Gordon, Director of the Alliance for Nuclear Accountability, an NCI representative wrote "The NCI has been and continues to be committed to fully informing the public about the results of (the I-131) research". This statement is directly contradicted by NCI's documented behavior. Not only did it take them ten years to execute research that fell far short of that mandated by Congress (see above) and then five more years to release it (under pressure), but there is documented evidence that they withheld information from the NRC panel, and that the panel appears to have accommodated passively to this refusal. (We quote here from the final draft NRC report. While this report was embargoed during the review process, we believe there is no barrier to quoting it now, following the release of the final report.) The Summary to the NRC panel's draft final report states: "The NRC panel received information from NCI indicating that their researchers had completed an investigation into whether available cancer registry data supported their estimates of excess thyroid cancer. Their analyses have not been made available to this panel (emphasis added). The NRC panel attempted a very preliminary analysis of limited epidemiological data from cancer registries to explore whether the data supported the NCI estimates of excess cancers."[6] This material does not appear in the NRC panel's final report.

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[4] The Review, page ES 8.

[5] The Review, page 137.

NCI is under intense scrutiny over these studies. No excuse that NCI might offer can justify this subversion of the committee's work. NCI could easily have shared their work with the NRC panel with some proviso that it could not be made public until review was complete. We believe that the Congress should not brook repetition of the long history of the DOE and its predecessor agencies of refusing to release data in their possession.

We also believe that the NRC panel has made serious errors by a) passively accepting NCI's refusal to share these data, b) wasting time and resources in an attempt to repeat work already done, and c) deciding not to inform you or the public about NCI's behavior in their final report. We shall further document, below, evidence that the NRC panel, while highly competent technically, produced a report that was markedly uncritical of NCI, but more importantly, expressed opinions on the health effects of low-level radiation that authoritative opinion views as far too optimistic.

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[6] Draft of The Review, dated 6/28/98 (" The Draft"), Summary, lines 152-156.

OFFER BUT DISCOURAGE: THE NRC SOLUTION FOR CARE OF THE EXPOSED

Here we shall attempt to clarify a complex issue. Before we do so, we bring to your attention two facts of paramount importance. First, the dispersion of I-131 is a government-induced problem. Thus, even though thyroid cancer is relatively infrequent, and of low lethality, the government owes its victims special consideration, since they, like veterans have sacrificed, willingly or not, because of a declared societal need. Second, the reported incidence of thyroid cancer has been going up since the time of atmospheric testing, while death rates have been going down.[7] The most logical explanation for the decrease is that treatment has been beneficial.

The NRC review states "Larger thyroid nodules (>1.5 cm) are more likely to be associated with clinically significant thyroid cancer. For several reasons, even these large nodules are not always palpable",[8] and later, " (A)nother study (Mazzaferri & Jhiang, 1994) suggests that once a thyroid cancer is manifested, delay in treatment lowers the survival rate.....The patients who died of cancer had a median delay (to the initiation of treatment) of 18 months from the time a tumor was first clinically recognized (by palpation) compared with four months for those who survived (P<0.0001)....The authors do not recommend screening for thyroid cancer but do argue for prompt assessment for large nodules (1.5 cm or larger) and prompt treatment for those diagnosed as malignant."[9] Mazzaferri and Jhiang drew this conclusion about screening although the NRC report states that they "(D)id not examine screening or screening benefits." [10]

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[7] Some of the increase in incidence could be artifactual, or in part due to radioactive fallout! Many people, especially as they get older, have either benign nodules or small areas of histologically cancerous thyroid tissue that do not progress to metastases or invasion of local tissue before they die from other causes. Thus, the rise in national incidence could be due in part to more complete diagnosis, rather than a real rise in frequency. (This is sometimes called "ascertainment bias".) It is noteworthy that the reported rise in incidence of thyroid cancer over the last decades is entirely consistent in magnitude with that estimated by NCI to be due to atmospheric weapons testing, suggesting that it is not an artifact. In contrast, there is no obvious artifactual cause for lower death rates from thyroid cancer. This has almost certainly been real, and a function of improved treatment.

[8] The Review, pages 33-34

Thus, we are told that early treatment is clearly beneficial, once the diagnosis of thyroid cancer has been made, but that screening is not recommended. What is the rationale for this seeming paradox? Mainly it is that the vast majority of single nodules are benign adenomas, not cancers, but our currently available diagnostic procedures often leave it unclear whether the person has benign disease, small cancerous lesions that will never progress to invasive or metastatic cancer, or tumors that have a high probability of doing so. The larger portion "of thyroid cancers are occult tumors that are never detected during a person's lifetime."[11] Ultrasound examination may result in as many as 95% false positives. Fine needle aspiration is insufficient or inconclusive in 30 per cent or more of cases.

The central problem is that once thyroid masses or nodules are discovered, current diagnostic techniques are inadequate to predict with certainty those that are benign, those which are cancerous but may never progress, and those which will progress to potentially lethal invasive or metastatic cancer. The NRC review describes the imperfections of current diagnostic methods. In order to detect large nodules that are more likely to be malignant (those over 1.5 cm. in size) and 75% of which are assumed to be palpable, we are told that 10,000 screening examinations (age not specified, not at high risk) would find 39 such cancers but miss 101 in smaller nodules, and, just as importantly, would result in 363 unnecessary thyroid lobectomies to find those 39 cancers.[12] There is thus significant risk that screening could lead to the removal of many normal thyroid glands, or those containing lesions that pose no threat to health, as well as leave many cancers undetected . Once the thyroid gland is removed, the individual will need lifelong thyroid hormone replacement; the surgery also puts the individual at risk for the removal of the essential parathyroid glands, or damage to the laryngeal nerve, impairing normal speech.

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[9] The Review, page 85

[10] The Review, page 85

11 The Draft, Chap 3, lines 151-2

This is not, we repeat, not solely a problem arising from screening. The problem is shared by those patients who bring themselves to the doctor because of a lump in the neck (i.e., who arrive through no screening program whatsoever), and by people who seek a thyroid examination because they believe they have been exposed to radiation from fallout, again in the absence of an organized screening program. These patients are subject to the same uncertainties in clinical decision making, and the same potential complications from overtreatment. It is not that nodules discovered by screening should always be left alone, or that nodules discovered by the patient be aggressively treated; it is rather that our current methods for the diagnosis and prognosis of thyroid nodules are grossly inadequate.

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[12] The Review, Table 4.1, page 86

We believe that we are obliged to improve these techniques. This ignorance should be corrected by a well-funded and well-formulated research program.

The NRC panel states that "The lack of evidence that early detection of thyroid cancer through screening of asymptomatic persons improves health precludes a positive recommendation to screen...."[13]. This wording could mean that screening has been tried and has failed. **This is not so. Such screening, or some reasonable surrogate, has not been tested**. It is not that screening has proven to be of low utility, but that **in the absence of both better diagnostic and predictive methods, a serious test of screening may not be worth doing**; it is not responsible to recommend such a program until these methods are improved and have been put to rigorous test. We also cannot recommend screening now, but can forcefully recommend the research needed to replace this inadequate, interim non-response. The research that would make a secure and responsible recommendation possible has not been done, but you can require that it be done. The panel states "..there is no evidence that early detection of thyroid cancer through systematic screening (rather than through routine clinical care) improves health outcomes or has benefits that outweigh harm. It is still possible-given the lack of directly relevant research-that early detection through routine screening might offer some net benefit (emphasis added)".[14] We think such directly relevant research is obligatory. This does not necessarily mean massive, expensive and time consuming randomized trials of screening, since screening is not the central problem. Rather, it requires specification of which nodules and masses should be carefully followed, and which should be treated. The NRC panel request for such research is an aside of nine lines, not their highest priority, and not emphasized[15]. We believe, however, that it is of the highest priority. The nation needs accurate, quantitative information on the factors that are associated with likelihood of cancerous progression, as well as the rates of surgical complications, and how to lower them. To summarize, we know that exposure to radiation at early ages, female gender, nodule size and older age are associated with increased risk of cancer, and there is no reason to believe that a nodule of a given size in a person of a given age is any less lethal if discovered by screening, than if it arises from self referral.

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[13] The Review, page 92.

[14] The Review, page 97

Our current medical ignorance means that the policy of "offer but discourage" places a heavy burden on patients who are understandably anxious and fearful. Assuming that clinicians are fully informed and competent in thyroid problems, and that they are willing to take the time to discuss the pros and cons at length and answer questions fully, and that patients have the time and opportunity to read and understand the proposed informative handouts and other media messages--assumptions which in kindness can only be called highly optimistic--a short scenario might run as follows: "Mrs. Jones, you are 40 years old and you have a nodule about 1.25 centimeters in diameter. Thus, there is a 90 per cent chance that you do not have cancer; in the 10 per cent of cases like yours in which it is a cancer, it is usually not all that aggressive. If it is cancer, your risk of dying from it without treatment is about 5 per cent. Palpation alone doesn't answer those questions. If we go on to a fine needle aspiration, that test is inconclusive in 30 per cent or more of the time, in which case we will not know for sure if your lump is benign or harmless or if it might progress to a lethal cancer. We could do a thyroidectomy, surgically removing your thyroid gland, but the odds are high--though by no means certain--that we would be removing a normal thyroid. About six per cent of those who are operated on get complications, and almost all will need life-long thyroid hormone replacement. We will follow the size of the nodule regularly and carefully, and if it does increase in size, we will then examine some cells from it under the microscope. I therefore do not recommend surgery now. If, after we talk it over, you feel otherwise, given this balance of the pros and cons, we will follow your wishes."

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[15] The Review, page 140

We find the delay by NCI in completing and reporting their work all the more infuriating since it has probably delayed, possibly by a decade or more, the research necessary to improve our approaches to care for the victims of I-131 irradiation and others with thyroid nodules. The NRC panel's report strikes no note of urgency; yet, whatever research is ongoing to improve the sensitivity of diagnostic methods, and prediction of the clinical course of thyroid masses, should be expedited and expanded as a matter of the highest priority.

We also note that there would be little danger, and possibly considerable benefit, in screening for hypo- and hyperthyroidism, both well established (albeit infrequent) sequelae of irradiation. The NRC panel chose not to seriously consider offering such screening to those irradiated, barely touched on this issue, and omitted any recommendation for it. We believe it should be offered by the government.

SCIENTIFIC BIAS OF THE NRC PANEL

We believe that the NRC report is biased towards underestimating the effects of ionizing radiation on human health, as well as being exceedingly forgiving of the NCI's flawed response to their congressional mandate.

Examples abound. In their preface to the draft report, Drs Schull and Lawrence, co-chairs of the panel, stated "Perhaps fortuitously, relatively few of the 160, 000,000 Americans alive during the weapons testing program received cumulative doses greater than the exposure limit set forth in 1961, which would have amounted to 5 rem (50 mSv) exposure limit over a ten year period. This is approximately two and a half times greater than the average dose, 2 rem (20 mSv) estimated by the NCI investigators as a result of the fallout of I-131."[16] In the final review, this has been modified to "It appears likely that a relatively small proportion of the 160,000,000 Americans alive during the weapons testing program received cumulative doses of iodine-131 greater than the exposure limit set forth in 1961, which would have amounted to 5 rem exposure limit over a ten-year period."[17] This is deceptive, and both of these conclusions continue to promulgate NCI's misleading use of "average dose". Only milk drinkers were exposed, and the total dose was accumulated not by the "average" American, but almost entirely by susceptible young children, who were probably exposed to at least five to ten times the so called "average dose", far above the 1961 limits! We believe that the co-chairs have continued the misleading presentation of NCI, and that there were many exposed Americans, not relatively few.

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[16] The Draft, pages vii-viii

[17] The Review, page x

Further evidence of bias is that in their historical review, the NRC panel does not mention the suppressed USPHS studies of leukemia and thyroid cancer among those exposed to fallout, nor of DOE intransigence about releasing data. They underplay the difficulties the public has had in eliciting truthful information from the government.

Finally, there is evidence that the panel was polarized, and biased towards minimizing the effect of ionizing radiation on cancer. They state, in the draft report, "(T)he panel did raise questions about certain assumptions (of the NCI estimates of excess cases of thyroid cancer from fallout). In particular it noted that there is disagreement within the scientific community about the assumption of dose response linearity, that is, the assumption that even the smallest dose of Iodine-131 to the thyroid results in some excess risk of cancer."[18] This was subtly changed in the final report so that it no longer appears as the committee's idea, but only that of the faceless "scientific community": "(The committee) noted that there is disagreement within the scientific community about the assumption of dose-linearity, that is, the assumption that even the smallest dose of iodine-131 to the thyroid results in some excess risk of cancer".[19] There **has been** disagreement, but there is now near consensus by official bodies in the US[20] and internationally[21] that the effect of ionizing radiation on cancer is linear down to zero dose. By doubting the conclusions of these authoritative groups, the NRC panel places itself squarely in the camp of the radiation effect minimizers, and the neutrality of its conclusions is open to severe question.

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[18] The Draft, Summary, lines 146-149

[19] The Review, ES, page 5

[20] Committee on the Biological Effects of Ionizing Radiation: Health Effects of Exposure to Low Levels of Ionizing Radiation, Natl Academy of Sciences, 1990

[21] United Nations Scientific Committee on The Effects of Atomic Radiation: Sources and Effects of Ionizing Radiation, 1993
National Radiological Protection Board: Risk of Radiation-Induced Cancer at Low Doses and Low Dose Rates for Radiation Protection Purposes,

RECOMMENDATIONS TO THE CONGRESS:

After seriously considering all of these points, we believe that the Congress needs to take several specific actions:

a) Legislation is needed to supersede the present Memorandum of Understanding, which transferred responsibility for some -but not all- radiation epidemiology research from DOE to the Centers for Disease Control, but left significant control of funding with DOE. Such legislation should definitively transfer all responsibility for radiation epidemiology research, and all funding for such research, directly to the Centers for Disease Control. Such legislation should also insure outside oversight of ALL government financed or executed radiation research (say, by a group such as ACERER) and include public representatives (specifically excluded by NCI from its advisory committee for these studies). It is an open question whether the present leadership of NCI has so discredited the agency's work in this area that it would be inappropriate for it to participate in future work on the problems of fallout induced cancers in the U.S.

b) Demand that DHHS complete the mandate of your 1983 legislation. We urgently need to know the effects of testing for all major

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radionuclides, for all potential cancer sites.

c) Implement and fund assessment for thyroid disease other than cancer for all individuals at significant risk for exposure to ionizing radiation from fallout from testing of nuclear weapons, and from other government radioactive releases into the atmosphere, both inadvertent and deliberate.

d) Fund, urgently, research to improve prevention, screening, monitoring and treatment for thyroid cancer. This task will include refinement of screening and diagnostic procedures to better understand and improve their reliability and validity, in order to clarify which populations should be screened and monitored, and how. Explicit attention must be paid to gaps that currently exist in clinical decision making with respect to all individuals with thyroid masses, whether radiation-induced or not, and whether discovered by screening or by the patient. We believe the "offer-but-discourage" screening recommendation of the NRC panel is a reflection of serious weaknesses in current diagnostic and therapeutic methods; that "offer-but-discourage" is only acceptable as a stop-gap; and that the government, as the cause of much of this disease and psychological distress, is obliged to address this deficiency in our knowledge. This can be accomplished only by giving such research high priority and adequate funding.

e) Reopen consideration of the Federal Torts Compensation Act for those injured by nuclear weapons testing.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 5

NATIONAL RESEARCH COUNCIL
COMMISSION ON LIFE SCIENCES
2101 Constitution Avenue Washington, D.C. 20418

EXECUTIVE DIRECTOR

September 25, 1998

Honorable Susan M. Collins, Chairman
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Senator Collins:

On September 16, 1998, your Subcommittee held a hearing on the "National Cancer Institute (NCI) Management of Radiation Studies." As you know, the Institute of Medicine and National Research Council (IOM/NRC) recently completed an IOM/NRC study reviewing the scientific and technical soundness of the NCI study. We also provided NCI with recommendations on the implications of its study, including clinical-practice guidelines for evaluating and counseling exposed individuals--and on various research strategies likely to refine the risk estimates. Although, as you stated in your opening remarks, the scientific issues surrounding the NCI report were not the subject of your hearing, testimony about those issues and about the IOM/NRC study was submitted by Drs. Rush and Geiger. I am writing because their testimony contains a number of factually incorrect statements regarding the IOM/NRC report. These misstatements led Drs. Rush and Geiger to grossly incorrect conclusions about the IOM/CLS report, the process by which it was produced, and some of its authors. I am writing to set the record straight, and I respectfully request that this letter be made a part of the record of your hearing.

The most egregious error in the testimony and the one that was the basis for three of the nine points made by Drs. Rush and Geiger was the assertion that "there is documented evidence that they [NCI] withheld information from the NRC panel, and that the panel appears to have accommodated passively to this refusal." To support their accusation, they quote from the NRC/IOM panel's draft report, which had been sent to Dr. Geiger as part of our peer-review process. The fact is that shortly after the draft report was sent to reviewers, the panel received a copy of the NCI information it had requested, which is to be published in the *Journal of the National Cancer Institute*. Members of the IOM/NRC panel and its staff examined this NCI information and added a discussion of it in Chapter 3 (pages 62-64) of the NRC/IOM report, which was released on September 1. The statement in the earlier draft that the NCI analyses had not been made available to the panel was removed because it was no longer true. Dr. Geiger has acknowledged this error and asked the Subcommittee to modify his testimony. However, because this testimony was made available to the public, members of the Committee, and your staff with the allegation, it is appropriate that your hearing record show that the statements relating to this issue in the original testimony were in error.

The National Research Council is the principal operating agency of the National Academy of Sciences and the National Academy of Engineering to serve government and other organizations

Other points in the testimony take the IOM/NRC panel to task for not addressing the timeliness of the NCI study or what actions the federal government should take in view of the fact that it was responsible for the weapons testing that led to the exposures studied in the NCI report. Those topics while certainly appropriate for your committee to consider, are outside the technical, medical and scientific purview of this particular IOM/NRC panel and were not part of the subject assigned to it. When asked to perform a study, the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine strictly enforce a policy that the members of a panel not wander from the specific subject they were selected to address.

Drs. Geiger and Rush are critical of the IOM/NRC panel's discussion regarding a national screening program, although they do not differ with the recommendations. They also find the discussion of noncancer effects of I-131 to be too brief. We believe that the panel, made up of 27 individuals selected for their expertise and experience, has adequately reviewed and summarized the literature and current thinking on these issues. Moreover, it has provided the logic and rationale for its recommendations. This work was reviewed by 16 independent reviewers and the responses of the panel to the reviewer comments were judged to be satisfactory by a representative of our Report Review Committee which is made up of members of the Academies. The final report was approved for release as an IOM/NRC report. Drs. Geiger and Rush are correct in conveying the fact that the issues dealt with in our report are complicated and difficult ones, and we would be happy to discuss these issues at length with you or your subcommittee's staff.

I must address the charge that the IOM/NRC panel was biased. We go to great lengths to create well-balanced and expert study groups in all our work. If we discover an imbalance of views after we have formally reviewed panel members' potential conflicts of interest and biases, we modify the group. We believe that we did indeed achieve a good balance of both expertise and perspectives in the IOM/NRC panel.

In closing, I cannot leave unchallenged the personal attacks on the cochairs of the IOM/NRC panel, Drs. Lawrence and Schull. These gentlemen have each had distinguished careers, but more relevant to the charge made against them is that they stand out for their sensitivity to the underlying fact that we are talking about real people with real families when we study these issues. Their character is above reproach, and I believe that they are owed an apology by Drs. Rush and Geiger.

Senator Collins, thank you for your attention to this important issue.

Sincerely,

Paul Gilman

Paul Gilman, Ph.D.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 6

SUMMARY

	1996	1997	1998	1999	2000	TOTAL
Belarus Thyroid Study	556,000	535,200	759,200	945,600	1,145,600	3,941,600
Ukraine Thyroid Study	990,000	1,104,000	1,123,000	1,080,600	1,106,200	5,403,800
Ukraine Leukemia Study	518,600	242,000				760,000
TOTAL	2,064,600	1,881,200	1,882,200	2,026,200	2,251,800	10,106,000
Contributions						
DOE	1,837,600	1,717,700	1,785,700	1,939,700	2,164,800	9,445,500
NCI	227,000	163,500	96,500	86,500	87,000	660,500
NCI Personnel*	495,000	508,225	520,930	533,952	547,299	2,606,222

*Total contribution to all projects
Assumes an average of $200 per man-month

BELARUS THYROID CANCER STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	300,000	300,000	500,000	700,000	900,000	2,700,000
Local Assistance						
MINSK*	79,000	102,200	122,200	118,600	118,600	540,600
MOSCOW	30,000	35,000	40,000	40,000	40,000	185,000
Support	147,000	98,000	97,000	87,000	87,000	516,000
TOTAL	556,000	535,200	759,200	945,600	1,145,600	3,941,000
Contribution						
DOE	482,500	486,200	710,700	902,100	1,102,100	3,683,600
NCI	73,500	49,000	48,500	43,500	43,500	258,000
NCI Personnel**						

*Assumes an average of $200 per man-month

**Total contribution to all projects listed on summary page

UKRAINE LEUKEMIA STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	300,000	120,000	Projection			420,000
Local assistance	43,600*					43,600
Support	175,000	122,000	After Completion of			297,000
TOTAL	518,600	242,000	Feasibility study			760,600
Contributions						
DOE	431,100	181,000				612,100
NCI	87,500	61,000				148,500
NCI Personnel**						

*Covers 18 months period at $200 per man-month

**Total contribution to all projects listed on summary page

UKRAINE THYROID CANCER STUDY

PRELIMINARY BUDGET PROJECTIONS

	1996	1997	1998	1999	2000	TOTAL
Equipment and supplies	750,000	850,000	850,000	850,000	850,000	4,150,000
Local assistance*	108,000	147,000	177,000	169,600	169,600	771,200
Support	132,000	107,000	96,000	86,000	87,000	508,000
TOTAL	990,000	1,104,000	1,123,000	1,080,600	1,066,600	5,429,200
Contributions						
DOE	924,000	1,050,500	1,075,000	1,037,600	1,063,100	5,150,200
NCI	66,000	53,500	48,000	43,000	43,500	254,000
NCI Personnel**						

*Assumes an average of $200 per man-month

**Total contribution to all projects listed on summary page

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 7

6 Oct 98

To: Senator Susan Collins

From: Senator Ted Stevens

Subject: Re: 17 September 1998 hearing on Radiation-Related Diseases. Request to include materials for the record.

Madam Chairwoman,

I request that this request along with attached materials regarding workers in Alaska exposure to radionuclides be included in the hearing record. I also ask that a future hearing include the issue of Alaskans that may have been exposed to disease-causing radiation and chemicals at Amchitka..

Sincerely,

Ted Stevens

Attachments:

1. Alaska State District Council of Laborers report: Radiation Exposure on Amchitka Workers Backs Alaska Laborers Call For Worker Health Monitoring. Dated 31 March 1998

2. Testimony Prepared by Rosalie Bertell, Ph.D., GNSH, Estimating the Exposure to Ionizing Radiation Incurred by the Workers at the Amchitka, Alaska Site of Canniken Nuclear Test.

3. Indigenous Peoples's Council for Marine Mammals letter dated 9 November 1994.

4. Aleutian/Pribilof Islands Association , Inc. to Governor Tony Knowles dated 14, January 1998.

5. Dept of Environmental Conservation letter dated September 25, 1997, Re: Declassification of Amchitka Island Nuclear Underground Testing Related Documents.

6. Eberline Instrument Corporation letter to US Atomic Energy Commission dated December 4, 1972.

7. The Center to Protect Workers' Rights letter to US Dept of Energy dated May 5, 1997.

8. Letter dated 14 September 1998 from Mayor of Barrow, Alaska to Senator Susan Collins.

9. Alaska State District Council of Laborers letter dated August 19, 1998 to Sen. Ted Stevens.

10. Alaska State District Council of Laborers letter dated June 2, 1998 to Sen. Ted Stevens.

11. Alaska State District Council of Laborers letter dated September 9, 1998 to Sen Ted Stevens.

ALASKA STATE DISTRICT COUNCIL OF LABORERS
Laborers International Union of North America, AFL-CIO

2501 Commercial Drive, Suite 140
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Public Employee Local 71
Don Valesko, Business Manager
Laborers Local 942
Joe Thomas, Business Manager
Laborers Local 341
Mano Frey, Business Manager

Don Valesko
President

Andrew J. "Bear" Piekarsl
Business Manager/Secretary Treasurer

Press Release
3-31-98

RADIATION EXPOSURE REPORT ON AMCHITKA WORKERS BACKS ALASKA LABORERS CALL FOR WORKER HEALTH MONITORING

Today, the Alaska Laborers released a report from world-renown Radiation expert Dr. Bertell[1] which documents the concerns that workers at the Amchitka Nuclear Test sites have potentially been exposed to health-threatening radionuclides. The report represents the workers own efforts to review their radiation exposure levels, since the government has failed to act yet on the workers concerns.

Following the unexpected death of Alaska laborer Nick Aleck from myelogenous leukemia, his widow Mrs. Bev Aleck has fought for years to get straight answers on her husbands death and the health hazards all workers faced from the federal government's nuclear tests, Long Shot, Milrow and Cannikin, 1965 - 1973. Other affected Amchitka workers (include those civilians employed on the the Navy's Over-The-Horizen Radar site in the 1980's - 1990's), and their widows have also been suspicious of the inordinately high rate of cancers associated with radiation exposure.

The Alaska Laborers are frustrated with the failure to date of the DOE, or anyone in the federal government, to take any constructive action to conduct a medical survey of the people, or study the workers' health directly, or provide preventative medical care. Nothing helpful has been done.

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[1] Dr. Rosalie Bertell Ph. D. currently serves as President of the International Institute of Concern For Public Health since 1987. Dr. Bertell has also served as a consultant to U.S. Nuclear Regulatory Commission; the President's Committee on Three Mile Island, the Marshall Island's nuclear test review; and served on the Permanent People's Tribunal for the Bhopal India (Union Carbide disaster) in 1992 - 1994. She has also published over 90 public health articles including Worker exposure to Ionizing Radiation as well as the Chernobyl Nuclear disaster. Since 1951 she has been a member of the Grey Nuns of the Sacred Heart.

***

For the Union A.J. Bear Piekarski said, " I worked in the Amchitka Cannikin shaft with Nick Aleck and others who have either died or now have cancers. I was the Job steward then and they told us there was no radiation-exposure -- now we know different from the feds own declassified documents! The government needs to come clean with Alaskans on this and remember these are People we're talking about. The feds are now studying Amchitka's (Atomic Tests) affect on the TUNDRA, how about the PEOPLE!"

The union's attorney Kevin Dougherty repeated the call for DOE to step forward and fund a medical survey of the workers health. "From the government's own documents we can see that a study of the workers is absolutely warranted so we may determine the level of health effects and precautions the people should take. We should not underreact or overreact, but must responsibly inform these workers about their health. Time is critical to human health so we can't have further delay. We need to get immediate review of these workers. And as the responsible party DOE must step forward."

Specifically, the Dr. Bertell Report reveals an exposure to Ionizing Radiation by Amchitka workers from:

- **Tritium Contaminated groundwater rained on the miners. [F-G]**
- **Cesium 137 vials "lost" in the shaft walls [470 mCi] in July 1969. [A-1]**
- **Neutron Tracer materials and Radionuclides stored and handled by workers on site and emplaced in Bomb cavity in August 1971. [A-3] [Fissionable material in the MeV Range]**
- **Krypton 85 & radionuclide gas released in 1972 drill back. [4000 cubic meters] [E]**

Most importantly, for verification purposes Dr. Bertell has relied on the government's own data from its reports and declassified documents.

Dr. Bertell's study concludes (p.8) with the finding that the Amchitka workers were exposed to ionizing radiation above normal background levels of **699 to 17,240 millerems (or more)**. This contrasts with the International Commission on Radiological Protection public safety level of 100 mrem per year or 5000 mrem worker level (currently 2000 mrem).

The serious health effects of radiation exposure has been codified in the Radiation Exposure Compensation Act of 1990 (and Radiation-Exposed Veteran's Compensation Act of 1988 which lists the "specified diseases" associated with Radiation exposure as:

A. Leukemia (other than chronic lymphocytic leukemia).

B. Cancer of the thyroid.

C. Cancer of the breast.

D. Cancer of the pharynx.

E. Cancer of the esophagus.

F. Cancer of the stomach.

G. Cancer of the small intestine.

H. Cancer of the pancreas.

I. Multiple myeloma.

J. Lymphomas (except Hodgkin's disease).

K. Cancer of the bile ducts.

L. Cancer of the gall bladder.

M. Primary liver cancer (except if cirrhosis or hepatitis B is indicated).

(Listing expanded since RECA enacted in 1990)

With this Report the Alaska Laborers call on DOE to finally take serious the need to get a Medical Surveillance study underway, and to do it promptly. Dougherty said, "Delay may jeopardize worker health and is inexcusable. We need to keep the workers informed so they can properly understand whether or not they have any health effects from their Amchitka work, and then take preventative action where necessary. The proposal submitted to DOE by Dr. Knut Ringen for The Center TO Protect Workers' Rights will develop a medical monitoring program of former Amchitka workers and research their death certificates. This study will be an add-on to the current Hanford and Oakridge nuclear worker's review.[9] Fortunately the Alaskans on the ATAG Committee have been strongly supportive of the workers' request for a Medical Surveillance review.[10] We thank them immensely. Now we trust DOE will finally get underway here."

The Bertell study was conducted at the request of the Alaska State District Council of Laborers, funded by the Laborer's International Union of North America, AFL-CIO, for the purpose of reconstructing radiation dose exposures to Cannikin miners,[a] and all Amchitka Workers during and after the three atomic bomb tests.

The Atomic Energy Commission, (AEC), and its contractors (generally) failed to monitor the radiation exposure of Amchitka union dispatched workers during the three atomic tests and clean up work conducted from 1965 to 1973, in violation of federal safety and health regulations, and Alaska State OSHA law.
(A bonafide epidemiology study cannot be conducted without ALL worker's radiatian exposure records.)

* They decided to monitor, the skiff (instead of the men)[b] to determine the amount of gamma radiation two locations of lost Cesium 137 (imbedded in the shaft) the workers were exposed to, during the cannikin cavity mining 1970-1971, and skiff stoppages.[c]
The workers have demanded these records. Now, DOE declares these monitoring records have been LOST.

* They were required to use special dosimeter devices, at the time Neutron capsule tracers, (or other devices) were emplaced in the bomb cavity during July - August, 1971.[d]
High tech federal personnel were monitored, and the special dosimeter union worker exposure records cannot be found.

* They ran into problems, during the drill-back in 1972, and released a large amount of Krypton 85 gas, without informing the general public or the union workers at the site.[e]
The workers have requested a complete analysis of ALL the elements contained in the 1972 KR-85 radioactive gas release.

* The "Cannikin Papers" classified in the early 1970's, prompted a lawsuit by Congress against the Government. (Patsy Mink v. U.S.)
The workers and ATAG members requested Declassification of the "Cannikin Papers"; and ALL of the elements in the Neutron Capsule Tracers emplaced in the Cannikin bomb cavity; and testing of the water[f,g] during the 1972 drill back, through the Alaska Department of Environmental Conservation (ADEC).[h]

Alaska workers are requesting equal treatment. It is known that AEC federal workers based on Amchitka for a period of time, also developed radiation related cancers, or are deceased, but received medical care and death benefits under Title 5 U.S. Code, funded by our tax dollars, with no questions asked. While Alaska workers who were sick or deceased could not obtain their medical care or death benefits because they could not "PROVE" their radiation exposure, due to the AEC withholding classified documents. This is not fair or just, having two classes of American Citizens at the same work site, and DOE needs to make amends post haste.

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Testimony Prepared by Rosalie Bertell, Ph. D., GNSH

Estimating the Exposure to Ionizing Radiation Incurred by the Workers at the Amchitka, Alaska Site of Canniken Nuclear Test

Enclosed:

Document 1: Summary of Data on Potential Worker Exposures to Ionizing Radiation, Amchitka, Alaska, 1968 to 1972.

Document 2: Special considerations relative to the former worker, Nick Aleck, who died in 1975 of leukemia.

Document 3: Curriculem Vitae of Rosalie Bertell

I declare that I have prepared these three documents myself, at the request of the Alaska State District Council of Laborers and Bev Aleck, widow of Nick Aleck.

Sworn before:
Date: February 13 1998
Toronto, Ontario, Canada

Sworn by:
Rosalie Bertell
Date: 13 Feb. 1998
Toronto, Ontario, Canada

Recipient of the Right Livelihood Award 1986
Charitable Tax Number 13053 1528 RT 0001

Summary of Data on Potential Worker Exposures to Ionizing Radiation Amchitka Island, Alaska

SOURCES OF EXPOSURE:

The worker exposures to ionizing radiation at Amchitka, above that due to normal cosmic and terrestrial exposures, were primarily due to:

1. Ground water transport of tritium from the underground nuclear test shot called Longshot.
2. Exposures associated with radioactive sources brought in, stored and moved out of the Birdwell storage structure or elsewhere on the site.
3. Exposures due to working in the shaft and cavity, including those from above normal levels from natural sources in the ground and those due to cesium sources embedded in the wall of the shaft.
4. Exposures related to subsurface diagnostic capsulated sources and the Radioisotope Thermoelectric Generators (RTG's).
5. Material released from the Canniken re-entry operations in 1972.
6. Exposures related to active and/or passive smoking of miners in the shaft and/or cavity.

Each of these potential exposures will be considered separately and then a maximum and minimum exposure estimate for a theoretical worker for one year will be estimated. Ionizing radiation exposures from special assignments and from the Canniken re-entry operation are also considered. It should be noted that exposure to residual radiation contamination of soil and surface water from the two prior nuclear tests on Amchitka was not well documented by managers of the Canniken shot in documents which I examined. Therefore, the estimate here calculated is likely to be conservative, i.e. less than the actual exposure of the Workers.

1. TRITIUM WATER CONTAMINATED FROM LONGSHOT IN SHAFT AND PIT.

Document 7-G, called Project PINOCCHIO, Seal Hunt II - Air and Water Sampling at the Long Shot Site, Amchitka, 13-24 November 1966, by Pierre E. Biscaye, noted significant radioactive krypton and tritiated methane in soil gas and dissolved in surface water near the Amchitka site attributable to Long Shot. Long Shot was an 80 kiloton nuclear device detonated at 2,300 feet depth one year before (1965). Test holes, including UA-1, the shaft for Canniken, were sampled above the 1525 feet depth. Some samples marked UAe were taken at different depths, but all were above 2000 feet deep. These measurements must have been primarily of air fallout, since the ground water flow would likely be into the next lower aquifer at about 2300 feet. No actual measurements of this contamination were found among the papers I surveyed.

Table 5 "Tritium Content in Amchitka Test-Well Water (NVO-1229-113 Part I) - August and September 1967 - reports tritium in UAE-1 sample ranging from 12 to 97 TU, or equivalently, 39 to 313 pCi/L. This also appears to be surface water measurement

Table II, B. Long Shot Surveillance Network Land, (Document 7-E) measurements in WELL-WL1 for 19 and 27 October 1969, show 930 and 3700 TU respectively. This is equivalent to 3000 to 12,000 pCi/L. The depth at which this sample was collected is not given, but it was presumably below the nuclear explosion affected aquifer. The values for the MUDPIT-A3 were intermediate to these values.

Exhibit 7, "An Interim Summary of Tritium Data for STS "A", Amchitka Island, Alaska July 1,1970 through June 30, 1971" by E. H. Essington (NVO-1229-172, UC-41): It is clear from the data that the tritium measured is not "old water" with about 1 TU, but it has been contaminated with surface water and also, likely ground water, which has been contaminated from Long Shot. At the bottom of the printed part on page 22 there is a notation that tritium was measured at about 20,000 pCi per liter. "Old water", with I TU would be expected to have 3.23 pCi per liter.

Table III Tritium Content of Amchitka Island Water Samples, A. Background network - Land, reports measurements during October and December of 1970, including BC-TAP-WH2 and UA-1, around 30 pCi/L in BC-TAP-WH2, and 3 to 10 pCi in UA-l.

Document 7-L "Hydrogeologic Processes and Radionuclide Distribution in a Cavity and Chimney Produced by the Cannikin Nuclear Explosion, Amchitka Island, Alaska. Geological Survey Professional Paper 712-D, Prepared on behalf of the U.S. Energy Research and Development Administration. WELL UAE-1, aquifer 3B, 5000 to 7000 feet depth, reports Gross Beta/gamma as 137 cesium equal to 18. This appears to be background levels before the Canniken shot, since the locations were sampled between 1964 and 1972 at Constantine Spring and between 1967 and 1972 at White Alice Creek. Since the background in UAE-1 was given at 282 cpm gamma (in Document 7-W), one can assume that the beta count was 5076 cpm, or about 85 counts per second. Assuming that this is tritium and the sample was one liter, this would imply about 2300 pCi per liter. I will make the assumption that the water at the bottom of the shaft in UAE-1 contained between 2300 and 20000 pCi/liter tritium. Because of the extreme heat in the pit (see exerpts from the tapes of Nick Aleck, May-August 1971: "It was sure hot down there. It must have been at least 140 degrees."), the tritium would have also been vaporized and inhaled. There is no indication that the men were tested for internal contamination. It would have been wise under the circumstances. Tritium has a relatively short biological half life. However, a fraction of the internal tritium is incorporated into organic molecules, said to be organically bound, and this has a biological half life of about three years.

Using the conversion factor from "Dose-rate conversion factors for external exposure to photon and electron radiation from radionuclides occuring in routine releases from nuclear fuel cycle facilities", by D.C. Kocher, Health Physics Journal 38: 543-621 (1980), namely immersion in water containing 1 microcurie of tritium per cubic centimeter (or 1 ml) is 5.26 X 10000 mrem per year (or 6 mrem per hour), one can estimate:

> At 2300 pCi or 0.0023 microcurrie tritium per liter, or equivalently, 0.0000023 microcurie tritium per cc, workers in the mine working in the dripping water would be exposed to 0.000014 mrem per hour. Working a ten hour day, seven days a week for three weeks, this would be 0.003 mrem per four week work period. There were 13 such work periods in a year, meaning a likely dose of about 0.038 mrem per year maximum from this source.
>
> At 20000 pCi per liter the exposure would be 0.33 mrem per year.

Certainly some of the tritium would be in the water vapor, and would be breathed or ingested. However, this does not seem to be a major pathway for the average worker's exposure.

2. STORED RADIONUCLIDES ON SITE

Most of the radionuclides used in the operation were stored in the Birdwell Storage Structure. In this structure, according to Document 6-B, Eberline Instrument Report dated 4 September 1968, were scandium 46 and cesium 137. Scandium 46 has an 84 day half-life, and gives of 0.889 MeV gamma. It is highly radioactive and dangerous. There were seven cesium sources: two 35 mCi, giving off about 300 mrem/hr at 5.5 inches; three 200 mCi sources, giving off 1000 mrem/hr at about 7 inches and two 800 mCi sources giving off 4000 mrem/hr at about 7 inches. These are very strong sources. There was, additionally Pu-Be, Radium and Krypton 85.

Certainly workers unloaded these source when they arrived, placed them in storage and removed them periodically for use. Some workers must have supervised the storage facility. It is not believable that personnel radiation badges (TLD's) "nearly all of the time" read zero. General levels of radiation in the storage structure were 5 to 10 mrem/hour. Worker badges were designed to give cummulative exposures over one to three month periods (different time periods for evaluation were given on different documents). Assuming that the workers were involved in activities at the storage structure for, on average, one hour per week, their yearly exposure from this source would be between 250 mrem/year and 500 mrem/year. The maximum weekly exposure according to document 2-B, was 100 mrem/week or 3900 mrem/year. Some of the TLD's were apparently evaluated monthly (21 days of work at 10 hrs a day), and had a minimum detection level of 30 mrem. Therefore 360 mrem dose per year could have occured without detection by using TLD's.

3. BACKGROUND LEVEL OF RADIATION EXPOSURE AND EXPOSURE DUE TO WORKING IN THE SHAFT AND PIT.

Document marked Exhibit 12, dated 3/11/72, notes that background on Amchitka was measured at 30 cpm. This higher count may be due to the high latitude. Generally in the United States the background measurement is 10 to 20 cpm. Background in the shaft as measured in Document 7-W, was noted as 282 cpm for both mud and water at all depths. This is not unusual since all hard rock miners working underground are exposed to uranium ore bearing rock, and higher than normal exposure to ionizing radiation.

Workers averaged about 4 to 5 hours at a time in the shaft and/or pit at background radiation levels about ten times higher than they would have experienced from background radiation had they stayed on the surface of the island. The men worked ten to twelve hour shifts. My estimate would be that working on the surface of the Island exposed one to about 132 mrem per year background radiation. Working the shaft and/or pit added 0.135 mrem per hour. That is, to the 0.015 mrem/hour which would have been experienced in working on the surface, another 0.120 mrem-hour due the workplace being deep underground was added. At 10 hours per day, 21 days per work period, and 13 work periods per year, this adds 328 mrem/year above normal (surface) background to the worker's ionizing radiation exposure.

Another Document, dated 7/8/71 ODTL reported background radiation levels for the island at 2.3 mrem per week, or 120 mrem per year. This is close to the previous estimate, and using this for background would give 340 mrem per year added exposure due to underground mining environment.

There were two double cesium 137 sources in the wall of the shaft. At 64 feet above or below each of these sources, one embedded at 728 feet and the other embedded at 2341 feet depth, the radiation exposure was about 0.17 mrem/hour. The one foot area centered around the source measured above 3000 mrem/hour. A reasonable estimate of the dose average for the entire 128 feet vertical distance centered at one source would be 12 to 18 mrem per hour. One worker travelling in the man-cage down and up the shaft, once, would pass 4 X 128 feet or 512 feet affected by these two sources.

The entire round trip is 12,000 feet, so the contaminated portion is 4.3%. The total time for a round trip was given as 20 minutes, of which 4.3% or 0.86 minutes are spent in the cesium affected field. If this round trip occured at this rate, without stopping in the shaft, it would add between 0.17 and 0.26 mrem per trip to the worker's exposure. The average velocity of the man cage may have been much slower, based on worker experience of trips lasting one or two hours.

The average worker made two round trips per day (they surfaced for lunch), and they worker 10 hours a day for 21 days per work period, 13 work periods per year. Over the course of the year, the worker would have between 93 and 142 mrem additional exposure, if the round trips were actually accomplished in 20 minutes.

Allowance should be made for unexpected stopage while riding the man cage. Apparently workers did not always wear TLD's while working in the shaft or pit, and individual records of worker's exposures were not kept (or have been lost). About 64 men were employed as miners and they worked in the shaft and pit. The man-cage appeared able to carry 2 to 6 men at a time, usually carrying four or five in one trip. It made about 30 to 36 round trips a day, or 10,000 to 13,000 round trips a year. At a 10% failure rate, one can assume between 1,000 and 1,300 stopages in the shaft in a year, with about 32 to 40 stopages in the vicinity of the cesium sources. Assume also that when the man-cage stopped, it took an average of one hour to get it working again. Stoppage was apparently frequent enough that the radiation protection staff ordered that the eleven ampules of radioactivity to be emplaced in the shaft near the end of the excavation be sent down without a person in the man-cage so that there was no danger of anyone being stopped in the shaft with these sources.

Just based on random stopage and random place of stopage, one would expect a worker making about 546 trips in the man cage per year, to have experienced 54 stopagges of which 2.3 (on average) were in the vicinity of the cesium sources. Such prolonged time near the sources could result in exposures between 28 and 41 mrem. There would be higher partial body exposure near the center of the radiation field generated by the cesium source. Partial body exposures, for example exposure of an arm or leg, or abdomen, may have been as high as 3000 mrem near the center of the field.

4. EXPOSURE RELATED TO SUBSURFACE DIAGNOSTIC CAPSULED SOURCES AND RADIOISOTOPE THERMOELECTRIC GENERATORS (RTG's)

On or before 15 July 1971, eleven radioactive sources, capsules to be placed in a spherical dodecahedral array in the UAE-1 cavity arrived at Amchitka. They were stored for about five weeks and emplaced the second week of August. Installation required 3 people, who were expected to take 3 hours for emplacing all eleven capsules. Each capsule gave off neutron and gamma radiation. There was no indication in the Document marked Exhibit 8, that a quality factor for neutrons had been used for conversion of mR, as measured, to mrem dose.. For gamma radiation, the mR per hour measured is converted directly into mrem per hour. Neutrons are highly effective at inducing cell transformations, the first step in causing cancers, and are therefore multiplied by 10 when converted into a mrem dose. They are much more cytotoxic and carcinogenic than are gamma rays. There is also ~~evidence that the effectiveness of neutrons increases with a decrease in the dose rate, therefore they~~ [illegible] Academy of Science). According to the testimony of Dr. Jim Corothers on 12 December 1997 (510) 422-7010[LLL] they were fast neutrons, "fast spontaneous fissionable material... in the MeV Range". According to Corothers, the "O ring/ 4" x 1 1/8 Cylinder est. 700 mR/hr neutron".

For assessing the dose from neutrons, a quality factor should be used as a multiplier of the mR dose measured. I will assume the error in the reporting of the neutron dose, given as 48 mrem, since there is no mention of this conversion factor having been used and since under the circumstances, the estimate may be orders of magnitude too low.

Each one of the eleven capsules had a ring, called the "O ring", by which it could be held. In close quarters, I would estimate that the person would hold it about 1 foot from his body, with the capsule coming at about the midline. This midline dose could have been about 3.5 mrem/hr gamma and between 480mrem/hr (48 mR X 10) and 7000 mrem/hour neutron. Over a three hour period about two hours could have been spent actually holding a source by the ring and attempting to place it on the pre-prepared hook. The exercise may have given a radiation dose of 960 to 14,000 mrem. No TLD records for this operation were found, although according to Document 8-E, F., "Personnel dosimeters (TLD) will be worn by all personnel during the downhole installation of the capsules". Personnel were warned to stay at least five feet from the paint can containing the capsules, however this must have been difficult in cramped quarters and with the task of emplacement of each of the eleven capsules on hooks on the shaft and cavity wall.

If the men were being measured against the maximum permissible radiation exposure for members of the public, namely, 500 mrem per year, this job clearly involved an over-exposure. Nuclear workers were at the time permitted a maximum of 5,000 mrem, a limit which also was likely exceeded.

5. MATERIAL RELEASED FROM THE CANNIKEN RE-ENTRY OPERATIONS IN 1972

Exhibits 11, and 11 A through 11 L, refer to measurements made after the Canniken shot. Between January 1 and December 31, 1972, 4000 cubic meters of radioactive gasses were released, in the cleanup. The composition and this gas, and the release timing is given by Eberline:

Exhibit 11. Eberline Instrument Corporation estimated 4000 cubic meters of gases were released during periods in 1972; containing 0.25 curies 85 Kr, 4.0 millicuries HTO, 1.0 curies HT and 0.3 millicuries 14C:

Periods (1972)	Gas Volume (M^3)	Days	Daily Gas Vol.(M^3)
1 Jan - 20 Feb	130	51	2.55
21 Feb - 8 April	630	48	13.13
9 April - 21 May	1100	43	25.58
22 May - 23 July	1710	63	27.14
24 July - 15 Oct	220	84	2.62
16 Oct - 31 Dec	210	77	2.73
TOTAL	4000	366	

The average release of this gas was 11 cubic meters per day. The number of curies of Tritium released, whether as water vapor or tritiated gas, was about 4 times the number of curies of Krypton 85 released. Curies of Krypton released were on average almost 1000 times the number of curies of Carbon 14 released. An assumption is made that the gaseous mixture remained homogeneous over the year. Both Krypton and Tritium would have contributed measurable doses to skin, however, Krypton would have provided the largest whole body dose.

Between 5/25/72 and 6/3/72, 150 cubic feet of gas, containing 1 millicurie of Kr 85 was released. Since 150 cubic feet is about 4.25 x 10E(6) cubic cm, and 1 millicurie is 1,000 microcuries of Krypton, the gas concentration was about 2.35 x 10E(-4) microcuries per cubic cm. According to D.C. Kocher (Health Physics Journal 38:543-621, 1980, page 555), the whole body dose received from immersion in radioactive gas, with this concentration of Krypton 85, would be 1.23 x 10E(7) mrem per microcurie per cubic cm per year. For the release in question, this would be 8 mrem per day (assuming that the workers were exposed over the whole 24 hour period). A worker who spent 30 days on Amchitka, working under these circumstances, would receive about 240 mrem dose.

The combined skin dose from Krypton 85 and Tritium, would have been considerably higher, as much as 66 mrem per hour. Hence workers may later experience skin cancer. Both Krypton and Tritium can be breathed, pass through the lungs to blood and circulated throughout the body. A small portion of the Tritium can be retained in the body, the organically bound fraction, with a half life of 300 days. Dose to bone marrow from the Krypton, the significant dose in blood and bone disease etiology, would have been 10 mrem per day, or 300 mrem for a 30 day stay on the Island. Some workers may have stayed for as long as 90 days, and others may have stayed for only a few days. This radioactive gas would have been in both the work space and the living space of the Island. Krypton is a heavy gas, chemically inert but radioactive. It would stay close to the earth. It has a half-life of 10.72 years and eventually becomes distributed globally. Spasmodic releases would likely stay in the vicinity of the site for several days in calm weather. With a high wind, it might disperse quickly. I made the conservative assumption that there was no build up of Krypton, that is a complete air change in 24 hours. The doses to workers could have been higher in calm air, or if the gas contained radioactive particulates, and lower if there was a high wind.

Workers were also exposed to the contaminated waste at the cleanup site. There were nine 55 gallon drums measuring 0.57 mR/hour on contact, and five wooden boxes on skids, measuring 0.02 mR/hour. The documents state that: "All Birdwell sources are packaged in accordance with DOT regulations." Certainly the workers handled these sources and did the packaging. The date on 12 B is 16 March 1972, and there is a second Document 12 C which covers 16 July 1972 to 28 July 1972. I am estimating that the cleanup took place over two, two week periods, or over approximately 20 working days. I am also assuming that the handling and packaging of the Birdwell source materials and other miscellaneous cleanup of the contaminated site was at the 100 mrem per day level which was estimated for a workers maximum per week when this material was in storage. For twenty working days, the estimated exposure would be 2000 mrem, in addition to the exposure due to the Krypton gas.

Document 12 B contains a note written by L. O'Neill, relative to: "The Dowell sources (2 blending trucks with 50 mCi Cesium 137 sources) safely packaged, however, in my opinion the package does not meet DOT specifications." This would indicate that the package was physically secure but not properly sheilded. This would also pose a direct radiation exposure hazard for the workers. At about 18.6 cm (8 inches) from this source one would expect doses around 500 mrem per hour. Working around the trucks would have carried a risk of further exposure.

6. EXPOSURES RELATED TO ACTIVE AND/OR PASSIVE SMOKING OF MINERS IN THE SHAFT AND/OR PIT.

I considered the Document dated 1 May 1970, reporting a conversation with Ray Peters, a miner at Amchitka, in which he noted the fire hazard associated with working the shaft. I consider this incident to be a significant indication of poor safety practices at the shaft and pit. According to this dialogue, 110 gallons of oil had been pumped down the air pipe. It went to the bottom of the hole and was blown back up the casing where it mixed with the rust. This rust-oil mixture would burn if touched by a lighted cigarette. Apparently there was at least one fire at 4500 feet depth. This obvious fire hazard which went unchecked indicates an unacceptable level of safety consciousness.

It should be noted further, that there was a hazard for smokers resulting from the leaching of radon gas from the natural rock pierced by the shaft. Radon is about seven times heavier than air and would tend to settle near the bottom of the shaft. It was well known at the time that smokers in uranium and other hard rock mines experienced lung cancers at a higher rate and with a shorter latency period than did non-smokers. This excess for the miners was greater than could be accounted for by smoking alone.

There is a radioactive component in cigarettes, polonium 210, which is also one of the decay products of radon gas, the combination of these two sources was hazardous. Polonium 210 is stored in bone and can be implicated in bone cancer and some leukemias which originate in bone marrow. It appears that this hazard was not taken into account by workplace practice, nor was it reported as a risk to the workers. Even though the hazard of passive smoking had not been generally talked about at that point in time, it also was a reality in this workplace.

SUMMARY:

Ionizing radiation exposure above normal background levels experienced by the average worker at Amchitka per year were:	Estimated Minimum(mrem)	Estimated Maximum(mrem)
Due to tritiated gound water:	0.04	0.33
Due to stored Radionuclides on site:	250	3900
Due to below ground work site:	328	340
Due to "lost" cesium sources:	93	142
Due to accidental stopage of the man-cage:	28	41
TOTAL FOR AVERAGE YEAR:	699	4423

There were additional ionizing radiation exposures for men who had special assignments, or who helped in the cleanup after the Canniken detonation.

Extra due to encapsulated sources	960	14,000
Extra exposures due to Canniken Re-entry:		
Krypton 85 exposure	240	240
Handling and packaging of sources:	2000	2000
Dowell sources: (1 to 2 hours)	500	1000
TOTAL DUE TO SPECIAL ASSIGNMENTS:	3700	17,240

CONCLUSIONS:

Although the workers were apparently told that their work was not "hazardous", they were actually classified as nuclear workers, and were exposed to levels of ionizing radiation from non-natural and/or non-normal sources, above the level which at that time was permitted yearly for the general public, namely 500 mrem per year. In 1990, the International Commision on Radiological Protection, a body which the US helped to found in 1951, unanimously declared that exposures to the public should not exceed 100 mrem per year on a chronic basis. In fact, they found, in 1984, that 100 mrem a year exposure was an amount above which everyone agreed that the exposure was hazardous.

The estimated average exposures of workers were clearly in the range expected of nuclear workers, yet they did not have the protection of Radiation Safety Training or instruction in the proper usage of the Thermoluminescent Dosimeters (TLD's). The loss of worker's exposure records, or the failure to keep such records, was inexcusable since radiation protection formalities were well established by the late 1960's and early 1970's. The doses received by the men during special assignments and during the post-Canniken cleanup, exceeded the permissible quarterly dose of 1250 mrem and the maximum permissible yearly dose of 5000 mrem. In 1990, the ICRP recommended the reduction of worker exposures to ionizing radiation to below 2000 mrem per year.

Depending on how the doses were calculated, i.e., whether calendar year or work year was used, doses to workers may clearly have exceeded the 5000 mrem yearly maximum with the special assignments.

In my opinion these worker exposures can be expected to result in at least one or two excess radiation induced and radiation promoted cancers, and other ill health among the workers.

Rosalie Bertell

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9 November 1994

Bev Aleck
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Anchorage, AK 99515

Dear Bev,

I am sorry for the delay in reviewing the materials which you generously provided to me. I hope you do not mind but I have copied this letter to those listed at the end of the letter as I believe that what I see in this data will be interesting for them as well. Perhaps with everyone working together we all can get some clarification of our concerns.

I talked with Ron Klein at DEC on November 3rd. He informed me that the hazardous materials survey that was planned for Amchitka this fall was not funded. He anticipates that that work will be done next year. He did say the Navy flew in and took some samples in a few hours last month but that it was not a comprehensive survey as is needed and only looked at hazardous materials not radiation issues.

The EPA report from September [illegible] disturbing lines. I was interested to see that human blood had been sampled for ^{55}Fe were found to have a mean of 9,000 pCi/l, and urine for ^{3}H where levels up to 9,400 pCi/l were found. I was frustrated that there was no follow-up either over the short-term or the long-term. During their pre and post-tests they found that Adak residents had higher ^{3}H levels. It was also frustration to read that ^{137}Cs in local tests were higher than at the Nevada Test Site but lower than levels observed in more northern Arctic Villages. With this knowledge there has been no regular health follow-up studies for the residents in these communities with known elevated levels.

Adak's ^{3}H air level was up to ten times higher (at 4.9 pCi/m^{3}) than other areas (at .5 pCi/m^{3}). Attu's vegetation was the highest in ^{137}Cs at 3,400 pCi/l. Attu had the highest ^{3}H levels in the soil both in the top inch (410 pCi/l) as well as the next two inches (300 pCi/l).

Chignik was the highest in ^{137}Cs in the soil in the top inch (9.6 pCi/kg wet weight) and the next two inches (2.4 pci/kg ww). Marine foodstuffs had the highest ^{3}H readings at Mountain Village, Annette, Togiak, and Amchitka with readings of over 440 pCi/kg ww.

Were any of these indications of radioactive pollution from Russia? It appears likely. If so what about other western Alaska communities? Did they have similar levels and if so for how long?

It was also interesting to note that the post test Gross Beta radiation in water or snow which was measured was very consistent around the survey region with three exceptions. Those three samples were roughly 100 times the other samples (up to 320 pCi/l). They were the three samples taken in the ocean surrounding Amchitka after the test.

The article "Atoms and Otter" from the Anchorage Daily Times in 1971 was quite interesting. The fact that the researchers knew that the 1965 Longshot site was leaking ^{3}H within the first year and yet the information was not released to the public until 1969 after the Milrow test. This means that those working on the island were "downwinders" as well as being more directly exposed in the aquifers which poured in on them as they were drilling the Milrow shaft just one mile from the leaking Longshot project. They were all being exposed to the leaking tritium.

The loss of the U.S.S. Robert L. Stevensen with 4 million pounds of munitions on board was surprising in itself. Add to it the subsequent unsuccessful bombing which added at least another 2,000 pounds of explosives which did not detonate and 24 other bombs which could not set off the entire collection. Result, the Navy put a point on the map 16.5 miles southwest of Aleut Point on Amchitka as an exclusion zone. This collection of unexploded ordnance could eventually cause increased concerns over the potential for Amchitka to release its deadly load.

The LTMMP data reported on 21 September 1992 was the most difficult to go through. The background data is from 1977 through 1991, but not from before any of the tests for a baseline. The data was a bit frustration to sift through as it is arranged by site and therefore difficult to compare by date. It is particularly frustrating to see the lack of data at the three ground zero sample areas over time.

There were four readings which are so significantly different from the rest that I just do not know what to make of them. Three are from an area called the Decon Pond and are:

^{238}Pu 7.38E-06 pCi/l
^{239}Pu -4.92E-06 "
^{235}U 9.61E-04 "

The fifth is at the WL-2 site at Longshot where they had an alpha radiation reading of -8.92E-15 pCi/l. These are exceptional as all other readings only vary from factors of +02 to -03.

The balance of the data all appeared very well clustered as far as general levels. None indicate any major release nor releases that are currently considered biologically harmful. There were some interesting numbers which seem to indicate slight but regular increases.

Overall I would conclude that Longshot released ^{3}H for a number of years and that slowly the levels declined. Later levels of ^{90}Sr and ^{238}U and ^{234}U went up slightly. The Milrow test site also was showing slight elevations in ^{90}Sr in Cleaverge Creek and Heart Lake. I do not think that these two sources are contamination from Milrow but the gradual movement of some of the mid-weight radionuclides from Longshot in local aquifers. Cannikin I believe is leaking. It's ^{90}Sr was elevated in 1977. It is interesting to note that the highest levels of ^{90}Sr were measured around Cannikin in 1977 and never measured again or reported up to this 1992 summary. It was known that the migration of these radionuclides would take time, much longer than six years and yet no further testing has been done according to this report. This can been seen as very poor science or as an attempt to keep levels of concern from the public record.

I will list here the items that support the above statements. See attached maps for reference. * marks the highest reading I could find within the materials and compares the level to a rough average estimate of background levels. Please note these are not exact as I would need more time to breakout all the background levels per sampling year but I believe that the numbers do give an indication that more monitoring needs to be done for better information.

Aleck 11/94 - Hild

Longshot					
Mud Pit 1	^{238}U	1.26E-01	pCi/l	1982*	5xb avg.
	^{234}U	1.81E-01		82*	6xb avg.
	^{3}H	2.00E+03		77	
Mud Pit 2	^{3}H	2.50E+03		77	
Mud Pit 3	^{90}Sr	6.30E-01		77	
EPA-1	^{3}H	1.20E+03		77	
Reed Pond	^{90}Sr	2.10E+00		77	
Well GZ-1	^{3}H	5.30E+03		77	
	^{3}H	7.26E+03		78*	160xb avg.
	^{90}Sr	1.50E+00		77	
Well GZ-2	^{3}H	1.80E+03		77	
Well WL-2	^{3}H	1.01E+03		78	
Milrow					
Clevenger Creek	^{90}Sr	1.50E+00		77	
Heart Lake	^{90}Sr	2.00E+00		77	
Cannikin					
Cannikin Lake S.	^{90}Sr	1.80E+00		77	
Icebox Lake	^{90}Sr	1.60E+00		77	
Pit south of GZ	^{90}Sr	2.30E+00		77*	4xb avg.
HTH-3	^{90}Sr	1.70E+00		77	
White Alice Creek	^{90}Sr	2.30E+00		77*	4xb avg.
Cannikin Lake N.	^{90}Sr	2.20E+00		77	

Background levels 1977-1991 (b avg.)

average est.	^{3}H	4.52E+01
average est.	^{90}Sr	6.35E-01
average est.	^{238}U	2.40E-02
average est.	^{234}U	3.30E-02

Note: The multiplying factors with + and - signs after the letter E are key to understanding the above numbers. +03 means multiplying by a factor of 1000, +02 by 100, +01 by 10, +00 by 1, -01 by .1, and -02 by .01.

It is unclear at this time as to the potential environmental or health risks related these factors. It should not be assumed that when a level is for example five times the background average that it provides a risk more or less or equal to five times the background risk.

Aleck 11/94 - Hild

For your concerns on your late husband Nick's exposure I would think three things. First, he and all the workers at Amchitka were "downwinders." The island is known for its incredible wind. [illegible] been leaking [illegible] into surrounding water sources from the start and the information was not made public until after the work on Milrow had been completed. Nick's work on the Cannikin shaft was therefore within a few miles of a low level radiation source and had not been advised otherwise. You have stated to me that Nick told you that there were no warning signs and that during off time he had visited the two ground zeros. When he lived at the base for the Cannikin work he had to drive past the other two sites to and from his pit. You have also stated that the workers often fished in the local ponds and ate what they caught. It would be interesting to know which ponds were used and the possible levels of radioactive contamination that was in those fish. From all this, the workers on Amchitka appear to qualify as people living "downwind" from nuclear test sites.

Second, there is the source of the level of contamination in the mud pits at Longshot. If the radiation came from the drilling muds then the hole was obviously contaminated at the time of drilling. These do not appear to be NORM (naturally occurring radiological materials) which are part of regular mining operations. If the radiation did not come out with the drilling materials then the elevated levels can be assumed to be coming from the blast. Nick worked on the drilling of the Cannikin shaft and was in a constant rain of water from subsurface aquifers. It is possible that the radiation from either one or both of the previous tests had contaminated the aquifers, as is suggested from the creek and lake data at Milrow.

The attached DOE map of freshwater and aquifers indicates that the Cannikin shaft had to drill down through multiple aquifer levels and go deeper than the two previous sites. It also indicates that Longshot was well within the dynamic water systems under the island. It is interesting to note that the map only indicates water movement down from precipitation and out through the mass of the island. It does not mention that springs are feed from below and that fresh water on oceanic islands comes not from precipitation but from a fresh water dome that is maintained under the island. In either case the assessment of where these aquifers come in contact with either the terrestrial or marine environments needs to be monitored.

Third you mentioned the use of radioactive tracer materials in the concrete used to reduce or stop the flow of water into the pit. It would be interesting to learn more about that material, what was its level and source of radiation, and were any warnings, training, or protective equipment offered to any of the men working with it. This off course builds on the question of whether or not any information, warning, or personal protection equipment was given on potential risks from radiation that may be anywhere on the island from the previous tests.

You have mentioned that the workers were given film badges and that there were monitors in the shaft. The information on those measurements as well as the pre-Longshot baseline data would be most helpful. Likewise readings from deeper wells, or deep marine samples would provide much greater confidence in the claims of containment than surface and shallow well data which is provided in this report.

I cannot provide you with any certainties. The levels mentioned here are all relatively low. It is possible that Nick was exposed to higher levels. It is known that there was little or no warning given about the work or the other sites on the island. There is documentation that there was radiological leakage of Longshot. The questions are how much and of what. Clearly ^{3}H leaked and was kept secret until 1969. It appears that it may have provided for the elevated ^{90}Sr at Reed Pond, the Mud Pits, and in Well GZ-1.

It also now appears that the elevation of ^{90}Sr levels at the Cannikin sites in 1977 is an indication of contamination. However, with other sites on the island reporting similar levels it is unclear if this is a general level of local contamination. It is unknown if there are any difference from general background levels from other areas along the Aleutian Chain, in Alaska, or in the nation. The fact that no further sampling was done or reported just goes to raise more questions as to why.

There should be a long-term monitoring program in place for these three sites and the surrounding region. Unless there are regular reports to assure the levels are stable or going down we have no real confirmation that the containment is working. Under the initial report the lighter radionuclides, such as ^3H, could possibly begin to show in twenty to one-hundred years. We are just past that first marker and yet have no regular sampling program going on so that the public and in particular the residents of the region are made aware of the success of the containment. The 1977 data seem to indicate that there may be some release of the mid-weight radionuclides already, but with no further testing we cannot be sure. In this case no news is not good news; news of no change or decline is good news and well worth the required monitoring investment.

I hope that you can make use of this review for furthering you efforts to clarify the possible linkages between your late husband's work on Amchitka and his later disease. I believe that this information may be quite helpful to those concerned about the pollution of the Bering Sea. There are many people who depend on this region to provide their livelihood. If there has been a long-term, low-level source of pollution to the ground water which runs to the ocean this should be clarified.

Thank you again for sharing with me the testing records.

Sincerely,

Carl M. Hild

Carl M. Hild, M.S.Sci.Mgmt.
Biologist / Planner

enclosures: DOE maps of island and sampling sites

CC: Flore Lekanof, APIA
Larry Merculieff, St. Paul
Jane Rosenquest, Senator Stevens' Office
David Garman, Senator Murkowski's Office
Lois M. Joellenbeck, OTA
Ron Klein, DEC

Aleutian/Pribilof Islands Association, Inc.
401 E. Fireweed Lane, Suite 201
Anchorage, Alaska 99503-2111
Phone (907) 276-2700

January 14, 1998

The Honorable Tony Knowles
Governor of the State of Alaska
PO BOX 110001
Juneau, AK 99811-0001

Dear Governor Knowles:

The Aleutian/Pribilof Islands Association, Inc., supports the Amchitka Alaska Workers and the Alaska State District Council of Laborers in their efforts to secure funding from the Department of Energy for a health surveillance study of State of Alaska laborers who worked at the three underground nuclear test sites on Amchitka Island, from 1965-1967. Though a formal health survey of the health conditions of Amchitka workers has yet to be completed, a partial listing of worker health problems has been collected solely by a word-of-mouth process. This list documents a statistically significant number of workers who currently suffer or have died from various forms of cancers associated with radiation poisoning.

In response to Dr. Knut Ringen's proposed health study of Amchitka workers, Ralph Lightner, Director of the Office of Southwestern Area Programs, Department of Energy, states, "a study of this type is not warranted at this time." This is indeed a tragic oversight; a medical study concerning the health of these workers is not only imperative, but long overdue. As a member of the Amchitka Technical Advisory Group (ATAG), and primary stakeholder in the Aleutian/Pribilof Islands Region, we strongly support the enactment of a legislative appropriation to lend justice to a group of dedicated workers who sacrificed greatly for purposes of national security.

Sincerely,

Dimitri Philemonof

Dimitri Philemonof
Executive Director

DP/sd

cc: Bob King, Press
Tom Cashen, Labor Commissioner-Juneau
Al Dwyer, Labor Standards & Safety Director
Michele Brown, ADEC Commissioner-Juneau
John Katz, Gov. Knowles Washington D.C. Office
U.S. Senator Frank Murkowski
U.S Senator Ted Stevens
Congressman Don Young
State Senator Loren Leman
Dr. Knut Ringen, CPWR
Pam Miller, Greenpeace
Carl Hild, Institute for Circumpolar Health Studies, UAA
Bev Aleck, Alaska Workers
Andy Piekarski, AK State District Council of

TONY KNOWLES, GOVERNOR

DEPT. OF ENVIRONMENTAL CONSERVATION

Division of Air and Water Quality
610 University Avenue
Fairbanks, Alaska 99709-3643

Director's Office: (907)465-5360
Fairbanks Office: (907)451-2360
Fax: (907)451-2187

File: 2512.25.001

September 25. 1997

Mr. Ethan Merrill
U.S. Department of Energy
EM-45/Cloverleaf Bldg.
19901 Germantown Road
Germantown, MD 20874-1290

Dear Mr. Merrill:

Re: Declassification of Amchitka Island Nuclear Underground Testing Related Documents

There have been informal and formal requests made by stakeholders in the past year for declassification of documents related to the Amchitka Island Nuclear Underground tests. ur understanding is that DOE has been pursuing inventorying and declassification of many of ese documents. DOE, Nevada office, has been providing documents to the Department as they are declassified. The Department intents, in 1998, to complete its review of classified documents at the various DOE sites which are holding Amchitka materials and to request declassification whenever possible.

Currently, there are several documents that are of interest to the Department and other stakeholders that we are requesting copies of. and declassification if necessary. These are as follows:

1) Information on any tracers that may have been used in conjunction with the Longshot, Milrow, and Cannikin nuclear underground tests at Amchitka. Of particular interest, in this case, is the use of any tracers at Cannikin, and potential or actual exposure to workers.

2) The Cannikin papers, which consisted of a group of documents that reportedly contained Federal agencies' concerns with the Cannikin nuclear test that were kept secrete and sealed under Presidential order. Of particular interest are also documents relating to environmental and health effects concerns. rather than political or policy documents.

3) During the drill back into the Cannikin cavity, documents have indicated that water samples were taken and analyzed for radionuclides. As part of the review of the transport of radionuclides in the groundwater from the Cannikin tests, the Department is requesting this document.

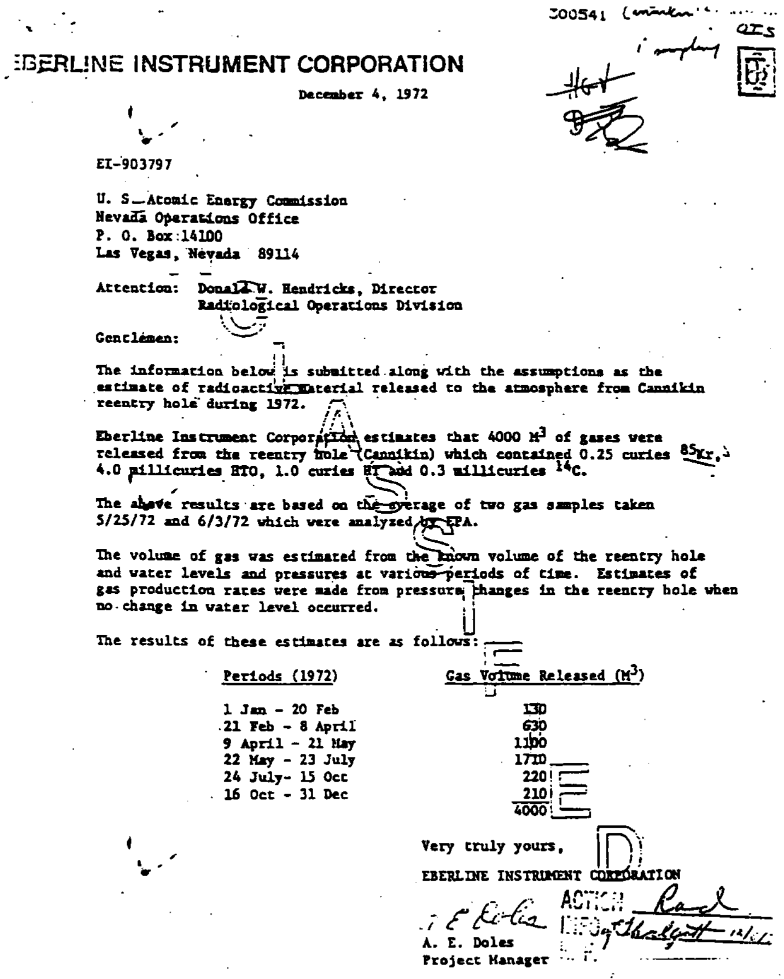
In cases where documents cannot be declassified, the Department requests the location and contact person information, so that a review of the classified documents can be made. DOE's efforts in locating of the documents and declassifying them is appreciated. If you have any questions, please contact Doug Dasher at (907) 451-2172.

Sincerely,

for
Douglas H. Dasher, PE
Environmental Radiation Program Manager

DHD/az (K:\AWQ\RAD\AIP\AMCHITKA\DECLASS.WPD)

cc:
Bev Alcok, Alaska Workers/Anchorage
Carl Hild, RuralCAP/Anchorage
Kelin Dougherty, Alaska Laborer's Union
Ted Stevens, US Senate/Washington D.C.
Frank Murkowski, US Senate/Washington D.C.
Pam Miller, Greenpeace/Anchorage
Ron King, ADEC/Juneau
Marideth Sandler, Alaska Governor's Office/Washington D.C



300541

EBERLINE INSTRUMENT CORPORATION

December 4, 1972

EI-903797

U. S. Atomic Energy Commission
Nevada Operations Office
P. O. Box 14100
Las Vegas, Nevada 89114

Attention: Donald W. Hendricks, Director
Radiological Operations Division

Gentlemen:

The information below is submitted along with the assumptions as the estimate of radioactive material released to the atmosphere from Cannikin reentry hole during 1972.

Eberline Instrument Corporation estimates that 4000 M^3 of gases were released from the reentry hole (Cannikin) which contained 0.25 curies ^{85}Kr, 4.0 millicuries HTO, 1.0 curies HT and 0.3 millicuries ^{14}C.

The above results are based on the average of two gas samples taken 5/25/72 and 6/3/72 which were analyzed by EPA.

The volume of gas was estimated from the known volume of the reentry hole and water levels and pressures at various periods of time. Estimates of gas production rates were made from pressure changes in the reentry hole when no change in water level occurred.

The results of these estimates are as follows:

Periods (1972)	Gas Volume Released (M^3)
1 Jan - 20 Feb	130
21 Feb - 8 April	630
9 April - 21 May	1100
22 May - 23 July	1710
24 July- 15 Oct	220
16 Oct - 31 Dec	210
	4000

Very truly yours,

EBERLINE INSTRUMENT CORPORATION

A. E. Doles
A. E. Doles
Project Manager

ACTION
INFO

UNCLASSIFIED

THE CENTER TO
PROTECT
WORKERS'
RIGHTS

ROBERT A. GEORGINE, PRESIDENT

KR

May 5, 1997

Mr. Ethan Merrill
Remediation Project Engineer
U.S. Department of Energy
Cloverleaf Building
19901 Germantown Road
Germantown, MD 20874

Dear Mr. Merrill:

Enclosed please find the proposal to develop a medical monitoring program for former workers of the Amchitka testing facility, which we have recently discussed. The proposal is submitted by the Center to Protect Workers' Rights (CPWR) on behalf of the Alaska Building and Construction Trades Council. Participating organizations with CPWR on this project would include: the University of Cincinnati, the Occupational Health Foundation, the University of Washington, and Zenith Administrators Northwest, Inc.

The problems at the Amchitka site were referred to CPWR by the Alaska Building and Construction Trades Council at the recommendation of the National Institute for Occupational Safety and Health (NIOSH). The Alaska Building and Construction Trades represents the target population at Amchitka.

I have discussed this proposal with Dr. Paul Seligman from the Office of Environment, Safety and Health, DOE, and we propose that DOE fund this project as an add-on to DOE Cooperative Agreement No. DE-FC03-96SF21262 between the Department of Energy and the Center to Protect Workers' Rights.

I look forward to hearing from you.

Sincerely,

Knut Ringen, Dr.P.H.
Director
Enclosure

cc: Dr. Paul Seligman, Office of Environment, Safety and Health, DOE

111 Massachusetts Avenue, N.W. • Washington, D.C. • 20001 • (202) 962-8490 • FAX (202) 962-8499

1. Aims and Objectives

To assist in the development and implementation of a program of notification, medical screening and intervention for workers who may have been exposed to health hazards as a result of employment at the Amchitka testing facility. The specific aims are to:

- Identify and propose resolution to policy issues that surround this program, including coordination with DOE and its contractors and the unions involved.
- Conduct site health needs assessment and develop worker history risk characterization protocol as the basis to triage workers at risk.
- Develop worker notification protocol and related worker education materials.
- Establish a coordinating center to identify and locate the former workers, and schedule them for interviews and medical exams and data collection, provide for payment of providers and conduct follow-up with the affected workers.
- Develop a protocol for exposure history interviews and medical exams, including lab testing, and develop implementation plans for these, including quality control.
- Develop evaluation protocol to determine outcomes and worker satisfaction.

This application is submitted by the Center to Protect Workers' Rights (CPWR), which is the research and development arm of the Building and Construction Trades Department, AFL-CIO, in cooperation with the Alaska Building and Construction Trades Council, which represents the target population at Amchitka. This application builds on similar programs CPWR is engaged in at Hanford and Oak Ridge.

The work will be performed by a consortium consisting of the University of Cincinnati, the University of Washington, Occupational Health Foundation (OHF), and Zenith Administrators Northwest, Inc. (Zenith). This consortium provides outstanding expertise in all aspects of the work that will be required. The main responsibilities are identified in Table 1.

Table 1
Delineation of Main Responsibilities

Task	Lead Organization
1. Overall Coordination and Policy	CPWR
2. Risk Characterization	UC
3. Notification/Information Protocol	OHF
4. Exposure history interviews/Medical Examinations/Evaluation	UW
5. Implementation Management	Zenith

2. Background

Located in the Rat Islands of the Aleutian Chain, Amchitka Island is 35 miles long and almost 3 miles wide. The area encompasses 115.8 square miles of land and 161.2 square miles of water. In the early 1960s, Amchitka became a nuclear testing facility under the Atomic Energy Commission. The facility closed in 1995.

Amchitka Island was the site of three nuclear detonations conducted in October 1965, October 1969, and November 1971. Long Shot was a nuclear detection research experiment detonated at a depth of 700 meters (2,300 feet). It had a yield of about 80 kilotons. Milrow was a high-yield seismic calibration test detonated at a depth of 1,220 meters (4,000 feet). It had a yield of about one megaton. Cannikin, a test of a proposed warhead for the Spartan missle, was detonated at a depth of about 1,790 meters (5,875 feet), with a yield of less than five megatons.

Contamination present on the island is a result of the activities that began in 1943, when American troops landed to establish an airfield. In addition to the airfield sites, other contaminated sites developed during use of the island for the Distant Early Warning network between 1950 and 1961, during nuclear testing between 1964 and 1973, and during construction and operation of the relocatable Over the Horizon Radar between 1986 and 1993.

It is our understanding from the Building and Construction Trades Council in Alaska that the workforce employed at the Amchitka facility in positions that could lead to significant exposure to health hazards numbered approximately 300 workers, mostly in the building trades. This proposal is based on this estimate.

Section 3162 of the Defense Reauthorization Act provides for health monitoring of workers who have been employed at DOE sites. The participants in this project have extensive experience with these kinds of activities, and currently are engaged in three different DOE funded projects that respond to the requirements of Section 3162. The request to include Amchitka in these programs arise from the labor unions in Alaska. It should be noted that the Governor of Alaska and its Congressional delegations have requested that DOE establish such a program for former workers at Amchitka. It should further be noted that DOE has committed itself to a program of long-term environmental monitoring on Amchitka. The annual budget for this environmental monitoring exceeds the one-time budget for worker health monitoring proposed here by more than 3 times.

3. Organization

This project will be carried out by the following groups:

The Center to Protect Workers' Rights will coordinate the project, maintain contact with DOE and handle all policy and related issues that may arise. Dr. Knut Ringen, Director, will be responsible for the conduct of the program.

The University of Cincinnati will review and assist respectively in, risk characterization and developing occupational history questionnaires, and identifying and interpreting radiation-related health outcomes. Dr. Eula Bingham, Professor, Dr. Carol Rice, Professor, and Dr. Roy Albert, Professor, will be responsible.

The University of Washington will be responsible for developing exposure history interviews and planning the medical examinations and performing quality review. Dr. Scott Barnhart, Director, Occupational Medicine Clinic will be responsible for the technical content of the program.

The Occupational Health Foundation will develop all educational/information materials. Sandy Tillett, Director, will be responsible.

Zenith Administrators, Northwest, will manage the field operation, contract with medical providers, perform precertification review, assure coordination of benefits, maintain an 800 # hotline, verify that providers have followed protocol, secure all data before reimbursement is made, enter the data into a data base and maintain all records in accordance with Federal Privacy Act requirements. Marilyn Johnston, Claims Administrator, will be responsible.

4. **Relevant Experience**

- CPWR conducts one of the largest occupational safety and health research programs in the U.S., and specializes in developing consortia aimed at addressing major and very complex safety and health issues in the building and construction industry. It manages large-scale federally funded programs, including a DOE funded program to provide health monitoring for former building trades workers employed on DOE installations.

- CPWR and OHF are leading institutions organizing programs for building trades workers, including programs for former workers exposed to asbestos and other hazards. Key staff involved in this project developed the national model that exists for notification and intervention programs for workers at high risk due to past occupational exposure to health hazards.

- University of Washington is the leading center in occupational medicine in the Northwest with extensive experience in screening and evaluation of construction workers at high risk due to past exposures. It currently has two related projects funded by DOE at Hanford.

- University of Cincinnati is a leader in industrial hygiene evaluations and in the characterization of exposure risks in the construction industry, including task-based exposure assessment. It currently has a related DOE funded project at Oak Ridge. The University of Cincinnati will work in a consulting capacity to CPWR.

- Zenith Administrators Inc. is the largest claims administrator for multi-employers health insurance plans in the U.S., with offices in over 30 cities, where this work will be carried out.

5. Tasks to be Performed

In Year 1, we will carry out the work described in this section.

5.1 Task #1: Coordination and Policy

CPWR has prime responsibility for this task. We will plan for the organization of this program and coordinate its implementation to assure:

i. That the public health intent is maintained.

ii. That program implementation follows the plan and quality is assured.

iii. That data are collected in a manner consistent with the desire to conduct a thorough program evaluation, including epidemiological analysis.

iv. That DOE rules are observed, and DOE staff is fully informed, including submission of plans and procedures to a designated DOE Institutional Review Board. We will report regularly on progress.

5.2 Task #2: Site Risk Characterization

Drs. Eula Bingham, Carol Rice, and Roy Albert, University of Cincinnati, have prime responsibility for this task. A key element of developing and implementing the program at each facility will be to assemble the available information on occupational exposures at the facility. An immediate problem is to cull through the vast amount of exposure and risk assessment information that already has been collected. We will focus on the following activities:

i. Review and modify the protocol for worker exposure history taking being used at other DOE sites for applicability to Amchitka.

ii. Identify available data based on environmental monitoring (area sampling, etc.) The individual monitoring will encompass both exposure monitoring data (film badges, etc.) and biological monitoring (urinary uranium levels). Much of this information has already been assembled by DOE (or its contractors).

iii. Assess the available information for completeness, limitations, etc.

iv. Determine the extent that this information is applicable to subcontractor construction workers.

v. Define the need for and approaches to collecting supplemental information.

5.3 Task #3: Notification and Worker Education Protocol

The Occupational Health Foundation (OHF) has the primary responsibility for the development of the notification/worker education protocol. Past experience with high risk notification has found that an effective information program directed at workers, the community, and the media is critical. We would:

i. Review and modify the NIOSH notification protocol for use in this project.

ii. Develop worker and family educational materials and information for inclusion in notification materials and at local provider sites.

iii. Develop detailed plans for the functions of the local advisory committee.

iv. Develop plans for assisting local service providers in the development of education sessions.

v. Develop materials and plans for their dissemination to media and the community in each facility location.

vi. Develop plans for the evaluation of field service operations, including worker satisfaction with the program.

5.4 Task #4: Exposure History Interviews/Medical Examinations and Quality Review

The University of Washington (UW) has primary responsibility for this task. This task entails coordinating the exposure history interviews and planning the medical examinations and performing quality review. We would:

i. Modify the existing medical protocols developed for DOE projects.

ii. Locate medical providers, provide them with training and consultation, and conduct quality control.

iii. Establish a single laboratory facility to carry out tests.

iv. Develop and implement plan for data analysis and program evaluation.

5.5 Task #5: Claims Management System

Zenith Administrators will have the main responsibility for the development of claims processing and will manage field operations. Procedures will be developed for a commercial claims processing operation with national coverage to be established for the following purposes:

i. Developing eligibility file and verification procedure.

ii. Negotiating fees and establishing contractual agreement with local service providers.

iii. Developing claims management and reimbursement procedures.

iv. Locating individuals and scheduling interviews and medical exams.

v. Assuring coordination of benefits to minimize duplication of payment.

vi. Identifying sources of funding for follow-up care, and working with local providers to arrange such financing.

vii. Conducting follow-up with participants to assure satisfaction/service.

viii. Collecting data from local providers in accordance with the requirements of the Data Coordination Center and transmitting them to the Data Center.

6. Expected Level of Effort

In this program we will use a triage approach to minimize the use of medical testing and to maximize the use of resources. The triage design is outlined in Figure 1.

Assuming this to be the case, and based on previous experience in these kinds of programs, we believe that the project will involve the level of effort outlined in Table 2.

Table 2
Expected Level of Effort

Total population to be traced	300
Dead or lost to follow-up (40%)	120
Eligible for program	180

Expected location of eligible group	In Anchorage	Elsewhere	Total
Persons to be contacted	60	120	180
Expected refusal/nonresponse	20	60	80
Total number of interviews	40	60	100
No further information required	20	30	50
Total number of medical exams	20	30	50

Thus the level of services provided will be:

Population tracing	300
Searching for death certificates	120
Invitations to participate/follow-up	180
Interviews scheduled	100
Follow-up to collect medical records	50
Medical exams scheduled	50
Follow-up telephone interviews to determine satisfaction/needs	100

7. Time Schedule

June 1, 1997 -- September 30, 1997. Establish program and identify population.
October 1, 1997 -- March 30, 1998. Conduct health monitoring.
April 1, 1998 -- May 31, 1998. Analyze results and present report, including recommendations for additional health monitoring, if warranted.

8. Budget Estimate

This project will be conducted on a cost basis with a one-year budget estimated at $219,200. The budget is itemized in Table 3. The budget consists of two broad categories: (1) Program development and administration ($134,000), and (2) Service fees that will be reimbursed to providers for locating individuals, conducting health history interviews, and performing medical examinations where indicated ($85,200). No funds will be used for the purchase of fixed assets or equipment, and indirect costs will be limited to no more than 25% of personnel costs.

Table 3
Budget Estimate

Program development and administration		
CPWR Coordination	$39,000*	
OHF Educational materials	9,000	
UW protocol development and quality review	30,000	
Zenith Administrators program administration	56,000	
Total Program Development and Administration		$134,000
Service Fees		
Tracing 300 individuals @ $100	$ 30,000	
120 vital status search @ $50	6,000	
180 invitations/follow-up scheduling @ $40	7,200	
Conduct 100 interviews @ $150	15,000	
Schedule 50 medical exams @ $40	2,000	
Perform 50 medical exams @$500	25,000	
Total Service Fees		$ 85,200
Total estimated budget		$219,200

*This budget line also includes the University of Cincinnati activities.

9. Proposed Mechanism

The proposed mechanism for funding this project is as an add-on to DOE Cooperative Agreement No. DE-FC03-96SF21262 between the Department of Energy and the Center to Protect Workers' Rights.

10. Contact Person

Knut Ringen, Dr. P.H., Director
The Center to Protect Workers' Rights
111 Massachusetts Avenue N.W.
Washington, D.C. 20001
Tel: 202-962-8490
Fax: 202-962-8499
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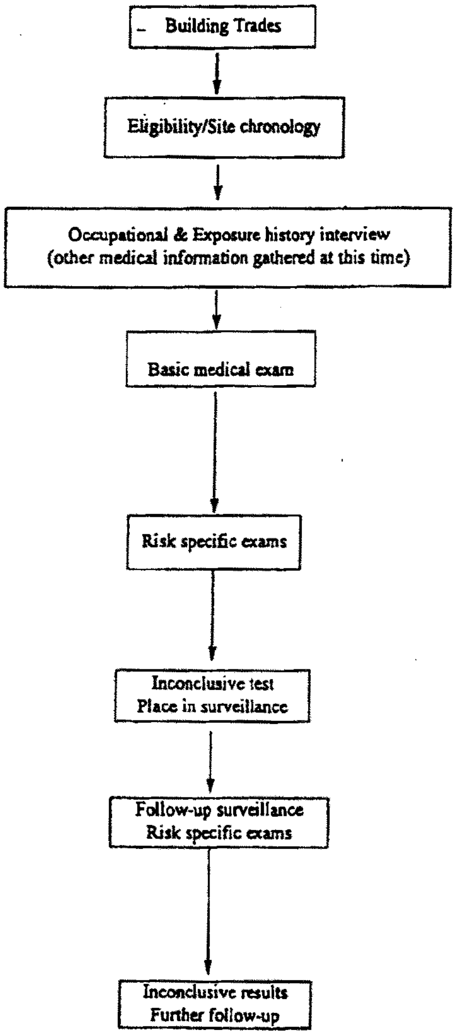
Triage Design



OFFICE OF THE MAYOR

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Senator Susan Collins
Gov't Affairs Permanent Subcommittee on Investigations
100 Russell Building
Washington, D.C. 20510

September 14, 1998

Subject : Iodine-131 Fallout Hearing
Senate Affairs Committee - September 17

Madam Chairwoman Collins,

We just received a letter from our good friends on the National Committee for Radiation Survivors. This information is critical to the Inupiat of the North Slope of Arctic Alaska.

As you may have heard, in the 1950's there was an experiment which was conducted by the Arctic Aeromedical Laboratory (AAL) , which was under the U.S. Air Force. The AAL conducted this experiment with a medical tracer, iodine-131, to determine whether the thyroid gland helps humans adapt to the cold environment. This project lasted from August 1955 to February 1957. The thyroid study's research subjects included 102+ Alaska native men, women, and children from villages in northern and central Alaska. There were also 19 military subjects.

In the experiment, capsules of the radioisotope iodine-131 were administered. The radio-iodide uptake in each subject's thyroid, blood, urine, and saliva was measured. This study is not addressed in the meeting you are having regarding iodine-131. The radio-iodide in the AAL experiments was ingested, not caused by any fallout.

Let me tell you what little I know of the Iodine-131. I know that this is a beta type of ionizing radiation. Ionizing radiation does not 'build up' in your body, however radiation effects may appear following exposure to large amounts of radiation. Over an extended period, the body can repair most small damage from almost any cause, including radiation, but if the dose is acute more serious damage will occur. Two kinds of radiation effects can occur : damage to the cells of your body (somatic effects) which may put you at risk, and damage to your reproductive cells (genetic effects) which may put future generations at risk. There are many different somatic effects but the most important long-term effect is cancer induction.

Health effects of radiation are divided into two categories : threshold effects and non-threshold effects. Threshold effects appear after a certain level of radiation exposure is reached and enough cells have been damaged to make the effect apparent. Non-threshold can occur at lower levels of radiation exposure.

Some threshold effects are : Possible cancers, blood changes, temporary sterility in males, genetic defects, bone growth retardation in children, radiation sickness, permanent sterility in females, bone marrow and intestine destruction, acute illness and early death (usually within days).

Non-threshold effects can occur at any level of radiation exposure, but the risk of harmful health effects generally increases with the amount of radiation absorbed. The most studied non-threshold effect is cancer. These studies are somewhat complicated by the facts that (1) not all cancers are caused by radiation, (2) exposure to a particular dose may cause cancer in one person but not another, and (3) the cancer does not appear until many years after exposure to radiation. It is currently impossible to determine which cancers are caused by radiation and which are caused by carcinogens within our environment.

Susceptibility to radiation induced cancer depends on a number of factors such as the site of exposure in the body, sex, and age. Sites in the body where cells rapidly grow and multiply, and those where radioactive materials tend to concentrate, are more susceptible than others.

One of the questions is whether the effect of low-level radiation is cumulative or whether it is harmful only if it exceeds some threshold value. Most of the evidence now seems to indicate that there are effects of both kinds. Some effects , such as cataracts of the eye's lens, do not occur as a result of radiation below a certain threshold, however others, most importantly perhaps the induction of cancer, do not appear to have any threshold and the risk of inducing such an effect increases with the dose. Tissues and organs vary a great deal in their sensitivity to the induction of cancer by radiation. As a consequence of exposure to radiation, solid tumors are now known to more numerous than leukemia. Solid cancers characteristically have long latent periods ; they seldom occur before10 years after radiation exposure and may continue to appear for thirty years or more after radiation exposure. Age is a major factor in the risk of cancer from exposure to ionizing radiation.

Genetic risk estimates to humans is based entirely on animal studies since no genetic effects due to radiation exposure have ever been demonstrated in human populations. Due to the effects being small and difficult to detect, due to abnormalities being high in the human population being in the norm, identifying the abnormalities are hard to detect. The abnormalities are mild, such as color blindness. The effects may not show up for many generations.

For effects of irradiation for which there is no evidence of a threshold dose, such as the induction of cancer, it is known that if a group of people are exposed to radiation then there will be incidences of cancer in that group. The more dose absorbed the more you are susceptible to cancer. It is known that exposure to ionizing radiation can cause biological effects that are harmful the exposed organism.

So far I have been recounting what I have uncovered from reading various material that have to do with the effects that are occurring to the experiment subjects of the iodine - 131 experiment of the Arctic Aeromedical Laboratory in the 1950's. This is only a mere fraction of experiments done to the Inupiaq people of Arctic Alaska. We have encountered countless accounts of different experiments. Some of these are in affidavit forms.

Some of the subjects of the said experiment (AAL) have died of the cancers which are probably (can be presumed) due to the experiment. The U.S. Government is not willing to own up to it, but, it is written in the technical report and the legacy of the Cold War nuclear research. The thyroid study discussed here differs from the fallout studies in that the radionuclides were actively administered to Natives without consent, no mention of risk to them, and subject selection, not to mention that the administered radioactive substance offered them no prospect of medical benefit.

In closing , I pray there is a comfortable solution and medical help for the subjects which are still alive and their children, and their children etc. (And the children of the deceased.)

Thank you,

CA Okakok

Charles A. Okakok
Special Projects Coordinator
North Slope Borough
P.O. Box 69
Barrow, Alaska 99723

cc: Senator John Glenn (D-OH), Ranking Member
Senator William Roth (R-DE)
Senator Ted Stevens (R-AK)
Senator Sam Brownback (R-KS)
Senator Pete Domenici (R-AZ)
Senator Thad Cochran (R-MS)
Senator Don Nickles (R-OK)
Senator Arlen Specter (R-PA)
Senator Carl Levin (D-MI)
Senator Joe Lieberman (D-CT)
Senator Dan Akaka (D-HI)
Senator Richard Durbin (D-IL)
Senator Robert Torricelli (D-NJ)
Senator Max Cleland (D-GA)

ALASKA STATE DISTRICT COUNCIL OF LABORERS

Laborers International Union of North America, AFL-CIO

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August 19, 1998

Honorable Ted Stevens
U.S. Senator for Alaska
522 Hart Building
Washington, D.C. 20510-0201

Dear Senator Stevens:

As the Alaska Laborers indicated in their August 11, 1998 letter, they would truly appreciate your assistance for the Alaska workers who have been exposed to radiation at the Amchitka Nuclear Bomb Detonation sites. The question by Senator Murkowski "to commit funding to the Amchitka Workers health surveillance program", to Secretary of Energy designee Bill Richardson, who responded negatively during his confirmation, was very disappointing. Therefore it appears extraordinary assistance is essential to overcome this deliberate DOE barrier to Alaska's Amchitka Workers health surveillance.

Amchitka Workforce: You may recall my initial contact with your office in 1994, regarding the death of my husband Nick Aleck, who was one of the miners who worked on the Cannikin project at Amchitka, and died five years later from leukemia. We have since learned that several other Amchitka workers also developed radiation associated cancers including leukemia. I was delegated by the Alaska State District Council of Laborers to represent the Amchitka Workforce at President Clinton's Advisory Committee on Human Radiation Experimentation, meeting held in Spokane Washington, November, 1994.

Thereafter, I was in close communication with your office and Senator Murkowski's office, attempting to add Amchitka to the **RECA Act**, by amending the existing Federal Regulations which named all of the Pacific Test Sites. Senator Stevens resolute stand on this issue is appreciated, and his support while fighting for the truth about my husband's death.

Following major releases of previously withheld classified information by Secretary of Energy, Hazel O'Leary, from 1994 through 1996, findings by Greenpeace indicated radiation contamination at Amchitka. Governor Tony Knowles on October 31, 1996 ordered an investigation of the Atomic Tests conducted on Amchitka Island, the impact on the Aleut Community, declassification of DOE documents, and a Medical Surveillance of former Amchitka Workers.

An Amchitka Technical Advisory Group (**ATAG**) was formed, consisting of Alaskan Stakeholders to: 1). Assist in planning the radiation sampling program at Amchitka and the marine environment; 2). To identify and request declassification of DOE classified and other documents; 3). To implement a Worker Medical Surveillance of former Amchitka workers.

Amchitka Legal Proceeding: I respectfully ask the support of Senator Stevens in my efforts to seek justice for my husband, Nick Aleck's death following his work on Amchitka. His wrongful death case was dismissed in 1983 because the necessary evidentiary records were withheld by US-DOE. Now the DOE's recently declassified records and independent expert opinions demonstrate the fatal radiation exposure Nick Aleck received at Amchitka. A press release by the Alaska State District Council of Laborers Concerning Dr. Bertell's report on Amchitka workers has been previously sent to your office. Dr. Bertell's report specifically concerning Nick Aleck is enclosed.

Based upon this newly accessible information, I unsuccessfully sought to re-open the lawsuit against the United States. My Appeal is supported by the Aleutian Pribilof Island Association, the Alaska State District Council of Laborers and Greenpeace. See attached Amici Brief. During oral argument last month in Anchorage, the Ninth Circuit panel suggested that the United States should attempt to settle the claim. The Order from the Ninth Circuit Court dated July 13, 1998 is attached.

Nick Aleck was an honorable American Veteran who served his country to the fullest in WWII. While enlisted in the U.S. Navy on aircraft carriers as a bombardier in both the European Theater and in the Asiatic Pacific, Nick Aleck was shot down and his carriers were sunk in three different incidents. Nick Aleck was hit by aircraft fire and was awarded the Purple Heart.

With this background, it is the greatest irony that the Federal government would fail to acknowledge his widow's rightful claim. The Amici and I believe it is absolutely essential that the Federal government settle this case out of simple respect and justice. Our Nation owes a debt of gratitude to Nick Aleck for his ultimate sacrifice in support of our National security.

I would greatly appreciate your suppport, and all efforts you can extend, in my effort to negotiate a just settlement with the United States, notwithstanding DOE's and DOJ's staid resistance, and bring final closure to this personal tragedy.

Thank you for your assistance.

Sincerely,

Bev Aleck

Bev Aleck
Amchitka Project

ALASKA STATE DISTRICT COUNCIL OF LABORERS
Laborers International Union of North America, AFL-CIO

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June 2, 1998

Senator Stevens
522 Hart Building
Washington, DC 20510-0201

Dear Senator Stevens:

As you know, many Alaskan workers were exposed to radiation at Amchitka. Therefore, we seek your assistance to redress the deaths and radiation-related cancers of our Alaskan workers from DOE's Amchitka Nuclear Tests through, 1). an amendment of the RECA Act, and 2). funding of a Medical Surveillance study.

The number of Amchitka workers who have reported cancers is devastating. Over 70 Alaskan workers, or their widows, have contacted us who suffer from those specified cancers linked to radiation exposure under the RECA Act of 1990. As reviewed by Dr. Rosalie Bertell's Report, and now confirmed by the government's own NIOSH 1998 Review, Amchitka workers were indeed exposed to ionizing radiation, without 'Rad Safe' dosimetry badges, from the following sources:

- Mineshaft Cesium 137 & Tritium
- Neutron Tracer Sources
- Radon progeny/NORM
- Strontium 90/RTGs
- Scandium 46
- Cobalt 60/Radiographic Cyclops
- Krypton gas & thorium 232 released in 1972 Drillback operations
- Fissionable product release from Cannikin Cavity Collapse[1]

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[1] The NIOSH 1998 'Preliminary Review of the Cannikin Project Records' found that the radioactive count rate increased 10 times in June 1972 from; 400 cpm to 4000+ cpm, with "several spikes of activity off the scale of the recorder". NIOSH p.5.

To give you an understanding of how these Alaskan workers suffer, here are a few examples:

Dick Coster: As an Alaskan Laborer, Coster worker in the underground shaft and was never informed of any radiation exposure or even issued a radiation dosimetry badge. While the federal AEC and LLL officials **WERE** badged to monitor their exposure, under a bureaucratic double-standard the construction workers were NOT given the same protection.[2]

Dick has been diagnosed with cancer and over 100 bone tumors throughout his body.

Ernest Blatchford: Mr. Blatchford worked at Amchitka in 1969-70 as an Equipment Operator/Local 302 along with his son Edgar Blatchford. Neither Alaskan worker was ever issued a radiation monitoring badge from DOE. Ernest Blatchford died of Thyroid cancer, a rare form of cancer which is associated with radiation exposure.

Merlin Oyoumik: Mr. Oyoumik is an Alaskan Native person from Unalakleet who worked at Amchitka in 1989-91. A few years after working in Amchitka he was diagnosed with Thyroid cancer. Two months later he also was diagnosed with stomach cancer. He is concerned with the health effects of Amchitka.

Bill Ferris: As an Alaskan Sheetmetal worker, Ferris was assigned to install a louvered fan on an Amchitka Radioisotopic Thermoelectric Generator. After two days with the RTG, an AEC agent ran up to him and said, " get away from that, this is a radioactive zone..., you're not supposed to be here.". The RTG's are powered by over 120,000 curies of Strontium 90.

Nick Aleck: Mr. Aleck died of Myelogenous Leukemia in 1975, shortly after working in Amchitka as a miner. As an Alaskan Laborer in the shaft, he was exposed to several underground sources of radiation. Myelogenous leukemia is the first- listed specified disease under the RECA Act. His widow Mrs. Bev Aleck has been especially active in investigating her husband's death.

Gary McClutcheon: Mr. McClutcheon worked as a Carpenter- Foreman/Local 1281 in Amchitka for two years. After the Nuclear blast he was back on Amchitka within two days and observed ruptures in the earth around Ground Zero indicating the Cavity Collapse referenced in the 1998 NIOSH Review (attached).

Mr. McClutcheon has been diagnosed with cancer and lymphoma, also listed as a radiation exposure specified disease under RECA.

Donald Bragg: Don Bragg worked as a miner in Amchitka in 1970-72. Mr.

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[2] See NIOSH "Preliminary Review of Cannikin Project" p. 2 documenting that DOE 1). either **failed** to badge the construction tradesmen entirely, or 2). only badged such workers **1 month** out the 30 months in the shaft operation from 1969-1971. NIOSH also found that DOE had lost records of high film badge readings. NIOSH p. 6.

Bragg's widow reports that when he returned from Amchitka, Don's hair fell out and his skin peeled off in a very unusual manner. [Two other Amchitka workers, Douglas Bee and A.J. Piekarski, also reported an unexplained loss of hair and skin peeling off immediately after returning from Amchitka.]
Mr. Bragg died of cancer in 1989.

Unfortunately, there are many more Alaskan workers who have died or currently have those cancers associated with radiation exposure, and they had no Rad-Safe Badging. Incredibly, the DOE officials were provided Rad-Safe badging for **their** own protection!

Most importantly, there are two **essential steps** the Alaska Laborers seek your assistance on:

AMENDMENT OF RECA

1). Your efforts to amend the Radiation Exposure Compensation Act, ["RECA"] to include the Amchitka Test Site, Alaska workers would be much appreciated.

Unlike all other test sites in the U.S. history, Amchitka was left off the RECA list. No rationale existed to exclude Alaska from the RECA compensation act, especially since the 5 Megaton Cannikin blast was the largest U.S. underground nuclear test ever conducted.
With the level of cancers[3] among the Alaskans who worked on the Amchitka project, these Alaskans deserve equal access to the RECA Act.

FUNDING FOR A MEDICAL SURVEILLANCE STUDY OF THE AMCHITKA WORKERS.

2). The Alaska Laborers request the funding of $221,000 to contract with Occupational Specialist Dr. Knut Ringen to do a Medical

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[3] The Radiation Exposure Compensation Act of 1990 lists 13 specified diseases which are associated with radiation exposure by workers. As the attached documents indicate, many of our Alaskan workers from Amchitka have died from or currently suffer from these specified cancers and myelogenous leukemia.

Surveillance Study of the Alaska workers who worked in Amchitka. Currently we have submitted a proposal to DOE for this Medical Surveillance study, as an add-on to Dr. Ringen's Hanford and Oakridge nuclear worker's review. Fortunately, the Alaska ATAG Committee members have fully supported this request for the protection of the worker's health. Since timely attention to worker health is important, we value all the assistance you can offer us on this funding request.

Senator Stevens, we have full confidence you can help us attend to one of the gravest health problem our Alaska workers have ever faced. Please call us if there is any further documentation we can provide. We also will keep the hundreds of former Amchitka workers informed of your help, and will readily make them available for public testimony, or any other information you request.

Thank you for your assistance.

Sincerely,

A. J. Piekarski
Business Manager

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September 9, 1998

Senator Ted Stevens
U.S. Senator
522 Hart Bldg.
Washington, D.C. 20510-0201

Dear Senator Stevens:

We understand that a Senate Governmental Affairs Permanent Subcommittee on Investigations hearing will be conducted on September 17th, 1998 regarding those radiation-related diseases now linked to DOE's Nuclear Weapons Testing Program.

First, we fully support this Senate Inquiry to address the serious health effects of DOE's Nuclear Weapons Tests, the government's failure to warn the public, and its unwillingness to disclose information and conduct Medical Surveillance programs needed for precautionary health measures for exposed workers.

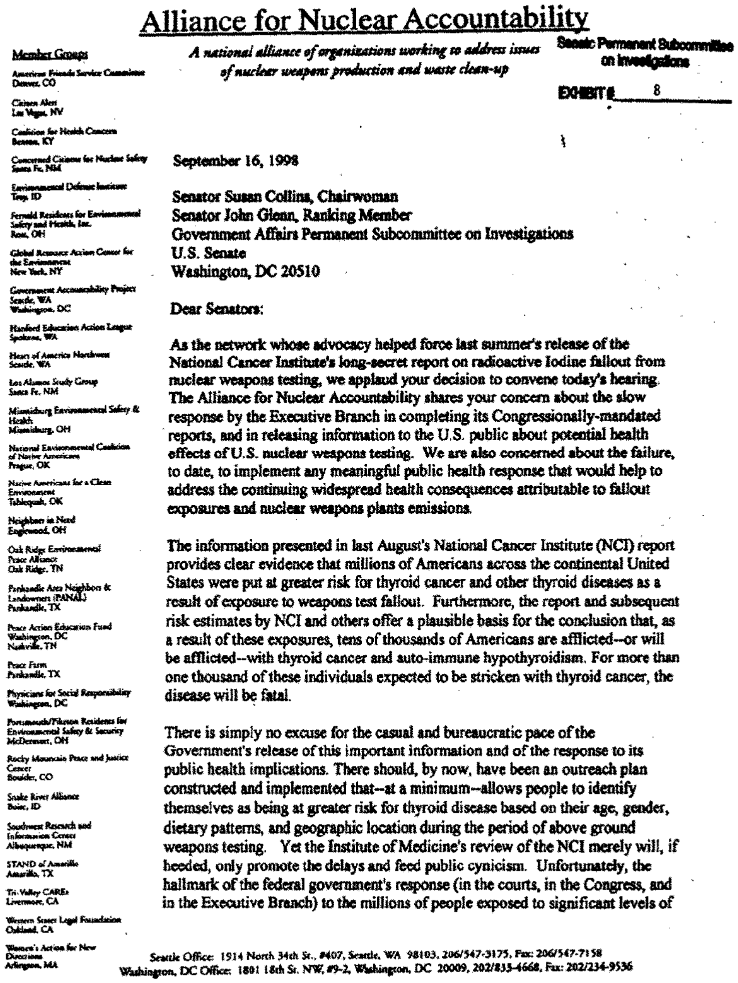
Specifically, the Alaska Laborers have faced enormous efforts by DOE to evade and cover-up fundamental information needed by the Alaska workers exposed to radionuclides at Amchitka. DOE's obstructive conduct is an insult to the basic American concept of open, democratic government.

Second, because of the Alaska Amchitka workers similar stake in getting fair treatment from DOE and Congress, we would appreciate your help in submitting into the Congressional Record our enclosed report on the Amchitka workers to assure that DOE and Congress does not ignore the Alaskans, as they have done in the past.

Thank you for your assistance.

Sincerely,

Kevin Dougherty



Alliance for Nuclear Accountability

A national alliance of organizations working to address issues of nuclear weapons production and waste clean-up

Senate Permanent Subcommittee on Investigations
EXHIBIT # 8

Member Groups

American Friends Service Committee
Denver, CO

Citizen Alert
Las Vegas, NV

Coalition for Health Concern
Benton, KY

Concerned Citizens for Nuclear Safety
Santa Fe, NM

Environmental Defense Institute
Troy, ID

Fernald Residents for Environmental Safety and Health, Inc.
Ross, OH

Global Resource Action Center for the Environment
New York, NY

Government Accountability Project
Seattle, WA
Washington, DC

Hanford Education Action League
Spokane, WA

Heart of America Northwest
Seattle, WA

Los Alamos Study Group
Santa Fe, NM

Miamisburg Environmental Safety & Health
Miamisburg, OH

National Environmental Coalition of Native Americans
Prague, OK

Native Americans for a Clean Environment
Tahlequah, OK

Neighbors in Need
Englewood, OH

Oak Ridge Environmental Peace Alliance
Oak Ridge, TN

Panhandle Area Neighbors & Landowners (PANAL)
Panhandle, TX

Peace Action Education Fund
Washington, DC
Nashville, TN

Peace Farm
Panhandle, TX

Physicians for Social Responsibility
Washington, DC

Portsmouth/Piketon Residents for Environmental Safety & Security
McDermott, OH

Rocky Mountain Peace and Justice Center
Boulder, CO

Snake River Alliance
Boise, ID

Southwest Research and Information Center
Albuquerque, NM

STAND of Amarillo
Amarillo, TX

Tri-Valley CAREs
Livermore, CA

Western States Legal Foundation
Oakland, CA

Women's Action for New Directions
Arlington, MA

September 16, 1998

Senator Susan Collins, Chairwoman
Senator John Glenn, Ranking Member
Government Affairs Permanent Subcommittee on Investigations
U.S. Senate
Washington, DC 20510

Dear Senators:

As the network whose advocacy helped force last summer's release of the National Cancer Institute's long-secret report on radioactive Iodine fallout from nuclear weapons testing, we applaud your decision to convene today's hearing. The Alliance for Nuclear Accountability shares your concern about the slow response by the Executive Branch in completing its Congressionally-mandated reports, and in releasing information to the U.S. public about potential health effects of U.S. nuclear weapons testing. We are also concerned about the failure, to date, to implement any meaningful public health response that would help to address the continuing widespread health consequences attributable to fallout exposures and nuclear weapons plants emissions.

The information presented in last August's National Cancer Institute (NCI) report provides clear evidence that millions of Americans across the continental United States were put at greater risk for thyroid cancer and other thyroid diseases as a result of exposure to weapons test fallout. Furthermore, the report and subsequent risk estimates by NCI and others offer a plausible basis for the conclusion that, as a result of these exposures, tens of thousands of Americans are afflicted--or will be afflicted--with thyroid cancer and auto-immune hypothyroidism. For more than one thousand of these individuals expected to be stricken with thyroid cancer, the disease will be fatal.

There is simply no excuse for the casual and bureaucratic pace of the Government's release of this important information and of the response to its public health implications. There should, by now, have been an outreach plan constructed and implemented that--at a minimum--allows people to identify themselves as being at greater risk for thyroid disease based on their age, gender, dietary patterns, and geographic location during the period of above ground weapons testing. Yet the Institute of Medicine's review of the NCI merely will, if heeded, only promote the delays and feed public cynicism. Unfortunately, the hallmark of the federal government's response (in the courts, in the Congress, and in the Executive Branch) to the millions of people exposed to significant levels of

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radiation from the U.S. nuclear weapons program is its aversion to accepting responsibility and providing anything meaningful in the way of help.

It is a basic concept underlying a wide range of government responses to health effects from toxic materials and other hazards that potentially affected individuals have a "right to know." Based on the National Academy of Sciences/Institute of Medicine recommendations released earlier this month, it seems the government would be putting itself in the position, once again, of making decisions about what exposed and potentially affected people should know and when they should know it.

If a private company had developed information indicating that large numbers of people faced injury or death from exposure to one of its products, surely the Federal government would expect, at a minimum, that strong measures be taken to notify those at greatest risk and encourage them to consult their physicians. The only difference in this case is that the contamination came from the U.S. nuclear weapons program.

Past efforts by the Atomic Energy Commission to mislead the American public about the human health risks of exposures to fallout are well documented. There is a pattern of ignoring the health effects of nuclear weapons production activities that includes suppressing information and denying access to historic records. In the courts, the Department of Justice has continually thwarted efforts for civil compensation by arguing, successfully, that governmental decisions that exposed millions of Americans to potentially harmful levels of radiation are protected by sovereign immunity.

Therefore, We urge you to use your full investigative powers to determine:

- why all the research required by Public Law 97.414, including any analysis of the health impacts of radionuclides other that I-133, was not completed in a timely manner;

- who was responsible for delaying the release of this important information to Congress and the American public;

- how federal research on the impacts of nuclear weapons testing and production should be reorganized to maximize protection of public health.

Thank for your leadership on these vital issues.

Sincerely,

Susan R. Gordon

Susan Gordon
Director

September 16, 1998

To: Government Affairs Permanent Subcommittee on Investigations

From: The Alliance for Nuclear Accountability

Re: The National Academy of Sciences/Institute of Medicine Review of the National Cancer Institute's report on Exposures of the American People to Iodine-131 from Nevada A-Bomb Tests.

We are providing our analysis of the review of the National Cancer Institute's (NCI) report on I-131 fallout from nuclear weapons tests completed by the National Academy of Sciences/Institute of Medicine (NAS/IOM). We are generally appalled by many of the intellectual weaknesses and general evasiveness of this review. For example, the extent to which the review attempts to assess the government's moral responsibility to those injured by fallout is a travesty; another cruelty inflicted on people whose lives and families have been greatly injured by exposures that the government both had the power to prevent and, at the very least, the power to mitigate through public health warnings at the time of the tests. The authors of this review live in a far better world than we do and their indifference to the legitimate expectations of downwinders is as transparent as it is disheartening. If, in the coming weeks and months, the NAS/IOM review is used as the basis for the United States government's decision not to provide a substantive medical response (as opposed to a public and medical information response) to people at highest risk from fallout exposures, it will break a lot of hearts and reopen many wounds.

1) Did the review deal honestly with the historical circumstances of the Nevada Test Site (NTS) exposures? Did the review assess the government's responsibility to provide medical screening within the special moral context of the historical circumstances?

No on both counts. Page ix: "Governmental decisions related to safety both on and off the Nevada Test Site were undoubtedly influenced by a sense of urgency about national security. One apparent consequence is a history of misleading government statements about the Nevada tests."

There is deep evidence that the Atomic Energy Committee (AEC) with the consent of the White House purposely misled the American people about the risks of fallout. For example, a March, 1957, AEC pamphlet advised "you people who live near the Nevada Test site" that "your best action is not to be worried about fallout."

Let's turn ahead to 1997. "..the credibility of the federal government in matters relating to exposure to ionizing radiation may have been compromised by the agency's perceived slowness in releasing the [NCI] report, once the analysis was largely completed."

Owen Hoffman asserts, and NCI documents support, the conclusion that "the calculations and analysis were essentially complete in 1992. The first results were known in 1989." It is simply inconceivable to believe that the National Cancer Institute--possessing the data and the analysis years ago, could have been ignorant of the public health consequences of its information. NCI cannot be excused for its indifference to the public health importance of this information--even if the wisest and appropriate public health responses to the information are not yet clear.

On the second question, with regard to how the NAS/IOM approaches the thorny issue of medical screening, the issue is whether the government's responsibility for the exposures (a responsibility profoundly deepened by its decision not to warn exposed people) fits into the decision about whether the U.S. should subsidize and encourage screening efforts. This issue was discussed during the NAS/IOM deliberations but not addressed in this report. It appears NAS/IOM was so confident in its demolishing of the arguments for thyroid cancer screening that it didn't feel the need to address this important ethical consideration. The problem is, not only is the thyroid cancer screening issue a less clear-cut call than the NAS/IOM would like readers to believe, but they've also backed off on the other possible and plausible medical screening responses, responses that are immune to the arguments used to weigh-in against the thyroid cancer screening.

Here's the basic philosophical question: In deciding whether to encourage or implement medical screening, should the government's decision be affected by the government's own contributions to the increased risk for the diseases in question?
We say yes. They say? They don't say.

2) What does the review say about the quality of the doses and risks presented by NCI?

On this issue, it appears the NAS/IOM has done a pretty good job. Its criticism of the county-by-county dose distinctions in the NCI report is measured and plausible. There are some who might read the NAS/IOM review to mean that the uncertainties in the NCI dose estimates reduces the likelihood that exposures were as far-reaching and high as the NCI calculated. But that's not what they mean. Indeed, readers should note on p. x of the report, the observation that "*..the number of persons receiving much higher doses [than the 1961 exposure limit of 5 rem], up to 100 rem or more, could have numbered in the tens of thousands.*" One of the key points that the NAS/IOM review reports on the issue of doses (see page 12-13) is that "individual dose estimates must be more variable than are county averages." This is key because the bulk of their criticism on the NCI doses has to do with the tenuous nature of extrapolating to geographic areas where there are radiation monitoring stations to those where there are not. But what they're saying, not surprisingly, is that it is your personal profile--who you are, how old you were, what gender you are, and what you were eating and drinking during that period--that is, in most instances, going to have a lot more to say about your thyroid dose (and risk) than where you happened to be living. Another way to look at this is that while location is most important in telling you whether you could have received a significant dose from fallout, it is much less important in determining how large a dose you may actually have received. One significant conclusion Department of Health and Human Services (DHHS) and others should draw from this (at least with respect to thyroid health issues) is that questions of personal risk should now focus more on personal information, rather than broader issues related to geography.

3) How well does IOM defend its decision not to recommend proactive thyroid cancer screening?

The report does not make a strong case against thyroid cancer screening. The consideration here is the ability to quantify benefits and harms--equations that are complicated because not all the benefits or harms are measurable in terms of physical outcomes. Some are, and the presentation on the potential physical harms of laryngeal nerve damage and injury to parathyroid glands is well done. Thus, those of us inclined toward screening would (even if we could successfully posit or document a benefit to some) have to confront the inevitable opportunity for causing physical and emotional harm to others who would be essentially recruited into the screening program.

What is surprising is that we expected strong documentation for the assertion that screening for thyroid cancer has no effect on outcomes. If this documentation were provided by the IOM we would not, and could not, even get into a examination of harm because any level of harm could not be justified. But the facts presented on pages 83 through 86 in the report are much different than that. At best, what the report can show is that we really don't know whether and how much benefit there would be to a thyroid cancer screening program. In the report's words, here's why:

"A major difficulty faced by the committee in considering its recommendations on screening for thyroid cancer was the absence of sound clinical research evaluating whether early detection of the disease through screening of asymptomatic people provides benefits in the form of longer life, reduced morbidity, or improved quality of life and whether such benefits outweigh any harms generated by screening. Rigorous prospective, randomized clinical studies of screening benefits are generally complicated, expensive, and time consuming. Ideally, they would randomly assign asymptomatic individuals to be screened or not to be screened and then track subsequent survival or other outcomes. No such studies of thyroid cancer screening have been published."

Further, the NAS/IOM reports that it found only one study (Ishida and others, 1988) that attempted any comparison of survival in screened and unscreened groups. While the study concluded that there was a benefit to screening, the NAS/IOM criticizes the results because of "critical design flaws."

About a related study, the NAS/IOM notes: "Although it did not examine screening or screening benefits, another study (Mazzaferri and Jhiang 1994) suggests that once a thyroid cancer is manifested, delay in treatment lowers the survival rate."

This is the sum of it: The committee discrediting Ishida for design flaws but noting there is evidence that delay in treatment for thyroid cancer lowers the survival rate. This evidence (the Mazzaferri and Jhiang reference) is not disputed. But it is mysteriously discounted. While it is not the study of screening that the committee is looking (in vain) for, it does lend support to those who believe, intuitively or otherwise, that if screening leads to early detection and treatment, it can positively effect the survival rate. In plain terms, there is still ample reason to believe (if not prove) that thyroid cancer screening can save lives. We suggest that the IOM/NAS is not entitled--by the weight of this evidence and reasoning--to have the last word on this question.

4) How does the IOM/NAS report deal with the Hanford Medical Monitoring Program (HMMP)?

Harshly. "[T]his committee concluded that research did not support systematic screening and that the Ishida study cited by Agency for Toxic Substances and Disease Registry (ATSDR) was seriously flawed and did not provide valid, usable evidence of benefit. DHHS will need to establish some process for managing or resolving this conflict. If political pressure prompts DHHS to decide to recommend or encourage screening, it should make clear that scientific evidence does not support the recommendation." (page 90)

The NAS/IOM reasoning is that because the positive conclusions of Ishida are not credible, therefore there is no basis for moving ahead with screening at Hanford. Ishida is not the sum of the justification for the HMMP. One of the considerations at Hanford, as with NTS, is that the at-risk population is an exposed population. The one in the Ishida study was not an exposed population and even if we can't accept a conclusion that the program benefited the women in the Gunma Prefecture that Ishida et al. studied, we should be open to the possibility that screening might be a net benefit to people who have been exposed, and particularly women entering the age of thyroid cancer vulnerability who were exposed when they were very young.

The other issue here is this jab with science. What makes the NAS/IOM statement about the role of "science" in this hard to swallow is that once again the burden of proof is borne by the victims. Typically, the burden is on exposed communities to prove they've been harmed when their harm, however genuine, is below the radar of epidemiologic detection, due largely to the small numbers in their communities. The IOM is saying that because of the profound absence of any science speaking credibly to the issue of whether thyroid cancer screening has benefit (or not), it shouldn't be recommended. This is oddly circular logic because it means that unless and until we study thyroid cancer screening programs to find out whether they work, they shouldn't be recommended. It may be that one valid reason to do thyroid cancer screening (albeit on a limited basis) is to get better answers on whether there is a benefit and, if so, how large or small.

If you read between the lines here (p. 90) what you see is the NAS/IOM criticizing ATSDR's "political" decision to do medical monitoring at Hanford when the proper "scientific" decision would have been to send out pamphlets. The Hanford Medical Monitoring Program isn't limited to thyroid cancer screening. It also includes blood test screening for non-cancer thyroid diseases, something the NAS/IOM review barely mentions or considers.

5) How does the NAS/IOM report deal with non-cancer risk issues and medical screening for hypothyroidism?

In his October 1, 1997 testimony before the Senate Appropriations Committee's Subcommittee that looked into the NCI report last year, Dr. Jan Beya expressed his concern that the IOM was going to devote inadequate attention to the non-cancer issues and not address the potential for screening for non-cancer outcomes. He was right on the mark.

The subject is addressed on pages 55 through 58 of the report. "Data on the induction of nonmalignant thyroid disease are inconclusive in the iodine-131 dose range to which most people were exposed from Nevada test site fallout." Last October, Dr. Beyea told Congress that autoimmune hypothyroidism and other noncancer thyroid diseases "should now be evident in the US population exposed to fallout doses of about 40 rads," and that if you look at the dose level where radiation triggers the anthithyroid antibodies that are the mechanism of autoimmune hypothyroidism, you can see this effect in the Chernobyl studies in the 0-30 rad range.

The NAS/IOM report summary on the bottom of page 57 states, "Overall (the) data clearly indicate that there is a highly significant association between ionizing radiation and the occurrence of nonmalignant thyroid disease at higher levels of exposure. It is also evident that this risk could extend down to the range of doses below 100 rad. For exposure to I-131, however, Maxon and Saenger (1996) indicate that hypothyroidism from I-131 would be unlikely at doses below 10 to 20 rad."

Remember the text from page x: "..the number of persons receiving much higher doses [than the 1961 exposure limit of 5 rem], up to 100 rem or more, could have numbered in the tens of thousands."

Yet in the very next line of the NAS/IOM report on page 57: "Thus, the data on nonmalignant disease induction are inconclusive in the dose range to which most people were exposed to fallout. As a result, the NAS/IOM panel did not further consider the implications of nonmalignant disease.

This is where the discussion of screening for non-cancer thyroid diseases ends, although the same conclusion is repeated virtually word for word on page 79.

It is indefensible that NAS/IOM essentially walks away from the non-cancer screening option by explaining that "most people" were outside the dose range of concern. At a minimum, this strange reasoning leaves us with tens of thousands of people, and possibly hundreds of thousands, or more, who were within the range of concern. It is remarkable, given the weight of the consideration given to benefit/harm considerations for thyroid cancer screening, that the screening option for non-cancer outcomes gets tossed off with such reasoning.

There is no argument (other than cost) that would discourage a screening program for hypothyroidism and the other thyroid conditions (including the early stages of Hashimoto's disease) that can be detected with blood tests. Given the weight of the government's responsibility for the widespread harm caused by these exposures, why shouldn't the government respond immediately with a blood testing program offered to those who remain at higher risk for thyroid disease because of these exposures.

6) How does the NAS/IOM review treat the issue of exposure to other radionuclides?

There is a decent discussion of this issue beginning on page 10 of the report that notes, among other things, that: "Some of the more prominent surviving radionuclides in global fallout are carbon-14, strontium-90, and cesium-137 that are incorporated into environmental media and food chains and persist for decades." It concludes with the following observation:

Given that work has already been done for iodine-131, it would be relatively easy to adapt the method for the additional radionuclides of interest though this exercise is not viewed as an urgent public health necessity."

On the other hand, the NAS sees the issue of additional research incorporating world-wide fallout differently. On page ES-8, summarizing its recommendations on "Further Research," the authors state "that such research was unlikely to benefit public health and would divert resources from other uses of greater probable benefit and this was well as the cost of such research should be clearly understood before a decision is make to undertake it due to public concern."

The "health" issue repeated here is a red herring. The public demand is for accountability. This, in fact, is why dose reconstructions are done around DOE facilities like Hanford and Savannah River and Oak Ridge--to document the exposures so that we can get a handle on risk in a way that will inform us as to what, if any, public health responses are necessary. The public accountability is necessary because of the secrecy and, in many instances, the lies told to exposed people downwind.

The NAS/IOM reviewers have lost touch with the realities faced by the human beings affected by the subject of this report. In doing so, they've completely and purposefully avoided the larger moral context in which these issues need to be weighed and considered.

There is a need to squarely address the harms of a thyroid cancer screening program. But we also need to factor in Constitutional rights, the betrayal of those rights by a Government that failed to warn, exposed, and then sought protection from civil actions behind the steel robe of sovereign immunity.

These issues make this more than a question of how you deal with masses of people at higher risk from radon or cosmic rays. These exposures were personal. They were misdemeanor assaults that could ripen, in time, to manslaughter. They touched and continue to touch real people and families. No one at the National Academy was speaking for these people and addressing their legitimate expectations for help.

Tim Connor of the Northwest Environmental Education Foundation was the primary drafter of this analysis.

Sep. 2, 1998

THE NATION'S NEWSPAPER
USA TODAY
NO. 1 IN THE USA . . . FIRST IN DAILY READERS

Panel: Don't test for fallout cancer

Cold War nuclear tests may be responsible for 75,000 cases of thyroid cancer, but scientists conclude screening may lead to 'needless worry and unnecessary surgeries'

By Peter Eisler
and Steve Sternberg
USA TODAY

WASHINGTON — The government should not test people for thyroid cancer linked to radioactive fallout spread nationwide during Cold War atomic bomb tests, a blue-ribbon scientific panel reported Tuesday.

The review by the Institute of Medicine (IOM) confirmed an earlier government report that fallout from the Nevada tests between 1951-62 caused or will cause about 75,000 thyroid cancers, though it could be as few as 11,000 cancers or as many as 212,000.

But in fulfilling its charge by the Clinton administration to recommend a government response, the IOM panel rejected medical screening — a course that could have involved hundreds of thousands of people and was pushed by some officials and citizen groups.

Screening "could result in needless worry and unnecessary surgeries because the tests used to detect the disease are so often inconclusive," said Robert Lawrence, a panel chairman and associate dean at Johns Hopkins School of Public Health. "This type of cancer should be detected and treated promptly during routine medical care."

The panel advised the administration to launch an awareness campaign to provide the public, physicians and local health officials information about fallout-related cancer risks.

Administration officials at the National Cancer Institute said they will review the report before deciding whether to accept the IOM recommendation.

"This is nonsense," said Sen. Tom Harkin, D-Iowa, who wants more federal studies on the fallout's effects.

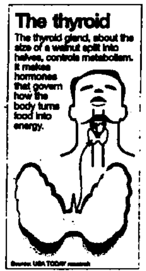
"There were adequate steps that could have been taken at the time (of the bomb tests) to protect people, and the government did not inform them," added Harkin, whose brother, Charles, died last year of thyroid cancer. "So there's a responsibility now to be more aggressive . . . and get people in for screening. Early detection and early treatment will improve people's chances for survival."

AP file photo

Atomic test: U.S. Marines watch a nuclear blast at the Nevada Test Site in May 1952. Nuclear testing from 1951 to 1962 released radiation that has been linked to cancers thousands of miles away.

The 100,000-page federal study under review spurred intense controversy when it was released last year, several years after its completion by the National Cancer Institute.

The study, first revealed by USA TODAY, traced fallout from the 100 above-ground atomic blasts at the Nevada Test Site. It identified counties thousands of miles away that got fallout at levels previously believed to be confined to areas immediately downwind from the site.

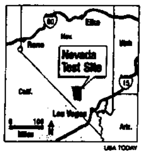


The thyroid

The thyroid gland, about the size of a walnut split into halves, controls metabolism. It makes hormones that govern how the body turns food into energy.

Source: USA TODAY research

By Bob Laird, USA TODAY



USA TODAY

The study focused on radioactive iodine 131, among the most prevalent fallout components. It was passed to humans through milk from cows and goats that ate contaminated grass. Once ingested by people, iodine 131 concentrates in the thyroid, where it has been linked to cancer, Graves' disease and hypothyroidism.

Children in the Rocky Mountain region and the Farm Belt generally had the highest risk of getting significant doses, the study found.

But the IOM panel concluded on Tuesday that the study, while useful in picking out regions that had high fallout levels, went beyond its scientific data in labeling specific counties as hot spots.

For that reason and others — including people's ability to recall their milk-drinking habits — the IOM said it would be difficult to identify individuals who should be medically tested.

"If we could identify populations with sufficient exposure, screening would be a wise choice," said William Schull, another of the panel's chairmen and a professor at the University of Texas.

The IOM also cautioned that screening might do more harm than good because suspected thyroid cancers often turn out to be benign — raising concerns about needless surgery.

Moreover, "even among those with exposure to iodine-131, few will develop thyroid problems," the IOM said.

Thyroid cancer is easily treated; about 90% of those diagnosed with thyroid cancer live longer than 30 years after the diagnosis.

However, critics said, the panel should have at least called for more aggressive public outreach, including explicit instructions that people who lived in high-fallout regions and drank a lot of fresh milk should see a doctor.

"If a private company had developed information indicating that large numbers of people faced injury or death from exposure to one of its products, surely the government would expect strong measures to . . . notify those at greatest risk," said Susan Gordon of the Military Production Network, a coalition of nuclear watchdog groups.

for further information:
Bob Schaeffer (617) 489-0461

Alliance for Nuclear Accountability

A national network of organizations working to address issues of nuclear weapons production and waste cleanup

for immediate release, Thursday, July 9, 1998

GROUPS WHICH EXPOSED SECRET NUCLEAR FALLOUT RISK STUDY CONDEMN LACK OF COORDINATED HEALTH RESPONSE DEMAND SEC. SHALALA ALERT DOCTORS AND U.S. PUBLIC

The national network of organizations which helped force last summer's release of the long secret National Cancer Institute (NCI) report on radioactive iodine fallout from nuclear weapons testing today called on Health and Human Services (HHS) Secretary Donna Shalala to take action to address public concerns about health effects from potential contamination.

In a letter to Sec. Shalala, the Alliance for Nuclear Accountability (ANA) wrote, "There is simply no excuse for the casual and bureaucratic pace of your agency's response to this information. There should, by now, have been an outreach plan constructed and implemented that -- at a minimum -- allows people to identify themselves as being at greater risk for thyroid disease based on their age, gender, dietary patterns and geographic location during the period of above ground weapons testing." When NCI released its fallout data last August, the agency promised a review by the Institute of Medicine within six months. That report is still not completed.

"If a private drug company had developed similar information -- indicating that large numbers of people faced injury or death from having used one of the company's products -- surely the federal government would expect appropriate measures to be taken to notify those at greatest risk," the ANA letter continued. "The only difference in this case is that the doses of concern came from contaminated milk rather than a pill or injection."

The ANA letter concluded, "There is no reason to wait a day longer to issue advice on steps that should have already been taken. Such information can make a difference in peoples' lives and, in many cases, is likely to prolong their lives if it allows early diagnosis of thyroid cancer."

A potentially fatal disease that can be caused by exposure to radioactive iodine, thyroid cancer is relatively easily treatable if diagnosed at an early stage. ANA urged HHS to provide public health officials and the public with information they need to identify who is most at risk and the symptoms that should lead to further medical examination.

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- Prior to January 1, 1998 the Alliance for Nuclear Accountability was known as the Military Production Network.
- The full Alliance for Nuclear Accountability letter to Sec. Shalala is available on request.

Member Groups

American Friends Service Committee
Denver, CO

Citizen Alert
Las Vegas, NV

Coalition for Health Concern
Benton, KY

Concerned Citizens for Nuclear Safety
Santa Fe, NM

Environmental Defense Institute
Troy, ID

Fernald Residents for Environmental Safety and Health, Inc.
Ross, OH

Global Resource Action Center for the Environment
New York, NY

Government Accountability Project
Seattle, WA

Hanford Education Action League
Spokane, WA

Heart of America Northwest
Seattle, WA

Los Alamos Study Group
Santa Fe, NM

Miamisburg Environmental Safety & Health
Miamisburg, OH

National Environmental Coalition of Native Americans
Prague, OK

Neighbors in Need
Englewood, OH

Oak Ridge Environmental Peace Alliance
Oak Ridge, TN

Panhandle Area Neighbors & Landowners (PANAL)
Panhandle, TX

Peace Action Education Fund
Washington, DC

Peace Farm
Panhandle, TX

Physicians for Social Responsibility
Washington, DC

Portsmouth/Piketon Residents for Environmental Safety & Security
McDermott, OH

Rocky Mountain Peace and Justice Center
Boulder, CO

Snake River Alliance
Boise, ID

Southwest Research and Information Center
Albuquerque, NM

STAND of Amarillo
Amarillo, TX

Tri-Valley CAREs
Livermore, CA

Western States Legal Foundation
Oakland, CA

Women's Action for New Directions
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Seattle Office: 1914 North 34th St., Suite 407, Seattle, WA 98103, 206/547-3175, Fax: 206/547-7158
Washington, DC Office: 1801 18th St., Suite 9-2, Washington, DC 20009, 202/833-4668, Fax: 202/234-9536

Fact Sheet

The Bomb's Lethal Legacy:

Producing and Testing Nuclear Weapons is Hazardous to Human Health

Radiation releases from nuclear weapons production and testing activities have exposed millions of people, world-wide, to higher risks for cancer and other potentially fatal diseases. Unlike the images of famine, war, or natural disasters, the human toll caused by these exposures cannot be directly observed. There are no photographs of devastated villages or of corpses lining river banks. Instead, the science tells us about a widespread, but largely silent, epidemic.

Who Was Exposed to Radioactive Fallout?

Analysts for the Institute for Energy and Environmental Research estimate that fallout from world-wide nuclear weapons testing will eventually result in between 215,000 and 430,000 fatal cancers. The estimate does not include the toll from the millions of curies of radiation released from nuclear weapons production facilities in the United States and in Russia. Nor does it include any estimate of non-fatal diseases that can occur as a result of radiation exposures.

This means that the health consequences of nuclear weapons production and testing are comparable to the worst known plague of the 20th century, the influenza pandemic of 1917-1918 which, in the United States, claimed the lives of approximately 400,000 people.

The health effects of nuclear testing were first brought to mass public consciousness in 1961 when a group of physicians and mothers identified strontium-90 in the teeth of North American children. A radioactive isotope, strontium-90, that is chemically similar to calcium accumulated in children's teeth when they drank the milk of cows which ate grass contaminated with fallout from atmospheric nuclear testing. Because fallout was so widespread, each child in the northern hemisphere who lived during the nuclear testing era was exposed to significant extra radiation doses.

More recently, uranium miners and the "downwinders" who lived very near the sites of US nuclear weapons tests have received some publicity and compensation from the government for their exposure and suffering. However, it is now clear that they are not the only ones who received unhealthy doses of radiation from nuclear testing. The National Cancer Institute's study of iodine-131 fallout made clear that nearly every person in the US at the time of a nuclear test was at risk. We are truly all "downwinders."

What Are the Effects of Exposure to Radiation?

Virtually everyone who lived in the US during the time of the above ground nuclear weapons tests between 1945 and 1962 was exposed to radioactive fallout. Fallout contained radioactive isotopes, such as cesium, iodine, plutonium, strontium, a variety of noble gases, and tritium. Some isotopes from nuclear fallout remain active in the environment for long periods, causing the particles to remain harmful for years, in some cases thousands of years.

Exposure to radiation from nuclear tests occurs by inhaling radioactive fallout particles, absorbing the fallout through the skin, and/or ingesting the fallout through contaminated food or water. Ingestion and inhalation are generally considered the two most dangerous pathways of exposure.

Alliance for Nuclear Accountability

(over)

Environmental Defense Institute
P.O. Box 220 Troy, Idaho 83871-0220 Phone 208-835-6152 / Fax '51

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 9

Comments on National Cancer Institute and Institute of Medicine Reports

Submitted on Behalf of the Environmental Defense Institute

By Chuck Broscious, Executive Director

September 21, 1998

The National Cancer Institute (NCI) report [1] on nuclear bomb fallout from the Nevada Test Site (NTS) identified five counties in the US most effected and four were in Idaho. The Institute of Medicine (IOM) review [2] of the NCI report contains (in appendix D) a Cancer Data Registry of Idaho report titled "Thyroid Cancer in Idaho, 1970-1996." This report concludes that "None of the four Idaho counties with highest estimated [based on NCI report] exposure to iodine-131 showed an elevation in thyroid cancer cases from 1970-1996."

Table 1 (Invasive thyroid cancer in Idaho, 1970-1969 among all birth cohorts) in the above Idaho Cancer Registry report however shows that all four counties identified in the NCI report (Custer, Blain, Gem, and Lemhi) had increases in thyroid cancer. Ada County experienced the most significant increase in thyroid cancer in Idaho (276 observed, 221.4 expected). The Idaho Registry report failed to disclose that Ada County borders Gem County to the north. Of the forty-four counties in Idaho, fourteen had an increase in thyroid cancer.

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[1] Estimated Exposures and Thyroid Doses Received by the American People from Iodine-131 in Fallout Following Nevada Atmospheric Nuclear Bomb Tests, A Report by the National Cancer Institute, October 1997

[2] Exposure of the American People to Iodine-131 from Nevada Nuclear Bomb Tests: Review of the National Cancer Institute Report and Public Health Implications, Institute of Medicine, 1998

An Idaho Division of Health report [3] reviewed a six county area around the Idaho National Engineering and Environmental Laboratory (INEEL). The report notes that, "The observed number of central nervous system cancers for the six county area was 110 (89 expected based on the rest of Idaho, p=0.013)." The report also notes that, "A significantly higher number of cases of brain cancer (182 observed, 151.6 expected, p=0.007) was reported in the six-county area for the years 1975 to 1994." This six county area (Bingham, Bonneville, Butt, Clark, Jefferson, and Madison) borders three of the four counties that the NCI report estimated with the highest I-131 doses.

A report written by Carl Johnson, MD and Michael Blain, Ph. D. reviewed federal data on cancer mortality and state data on cancer incidence in the six counties near INEEL. This report notes that, "When the Idaho state population is employed as a control group, there was an excess number of deaths (1950-69) from cancer of the more radiosensitive organs (17 observed, 9.4 expected, p=<.05)." "Mormans have a 23% lower rate of cancer than other populations and the six counties have large Morman populations (range = 40 - 80%)." "When the cancer incidence in the counties is compared to a Morman control population, there is an excess cancer incidence (1971-80) in Bannock (659 observed, 485.7 expected, p=.001, Bonneville (547 observed, 447.9 expected, p=.001), Butte (47observed, 34.5 expected, p=.05), and Clark (11 observed, 6 expected) counties." [4]

Sampling of Pronghorn antelope over a five year period in southeastern Idaho found Iodine-131 and Iodine-129 which resulted in significant doses to the animal's thyroid. The antelope were studied because they were considered good indicators to determining the likely doses received by the human populations. [5] Idahoans are less concerned about which US nuclear site the radioactive pollution came from, but they do want to know what the cumulative impact is and that the federal government compensate the individuals harmed.

The Institute of Medicine report notes that "Given the public concern about doses from iodine-131, further understanding of the risks to the U.S. population could be gained by a detailed evaluation of the dose and risks from the other radionuclides released by the atomic tests at NTS. Given that the work has already been done for iodine-131, it would be relatively easy to adapt the method for the additional radionuclides of interest though this exercise is not viewed as a urgent public health necessity." I fully agree with expanding the research to include other nuclides and other radiosensitive diseases, but vehemently disagree that there is not a public health necessity for the same reason that it was unconscionable for NCI to withhold the I-131 study for thirteen years. Additionally, the federal government has a moral/ethical obligation to tell citizens what cumulative dose they received from all domestic nuclear weapons operations. This by definition must include nuclear weapon materials production and reactor test site releases in addition to the bomb tests. The current piecemeal disclosure masks . total impact on public health. This is especially true for Idahoans because the state received doses from the Nevada Test Site, Hanford, and INEEL.

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[3] Idaho Public Health Brain Cancer Study, Idaho Department of Health and Welfare, Division of Health, Cluster Analysis Working Group, April 25, 1997

[4] Radioecological Effects on Animal and Human Populations Near the Idaho National Engineering Laboratory [sic], Michael J. Blain, Ph. D., Carl J. Johnson, MD, Carol F. Kreider, BS. , Robert W. Nicholas, BS, May 1985

[5] Commentary on the Scope of the EIS on Special Isotope Separation Project: Implications for Idaho, Michael Blain, Ph.D., March 11, 1987, citing:
Markham, O. D., Halford, D.E. et. al, I-131 Concentrations in Air, Milk, and Antelope Thyroids in Southeastern Idaho, 1980, Health Physics 38: 321-326 .

The NCI report that used average intake of I-131 is misleading and perpetuates the federal government's misinformation campaign of deception against the American people. Critics of the report offer credible evidence that the maximally exposed individual could have received 25 times the dose reported by NCI. [6] In the case of Idaho, that could mean a range of 300 to 400 rads to a small child drinking backyard cow or goat milk.

Funding additional health studies - even credible studies - does not constitute compensation to those individuals whose health is impacted by the federal government's nuclear policy. Congress has a responsibility to provide funding for medical monitoring and care for effected populations. Due to the wide range of health outcomes from radiation exposure, a general default health care program must be offered. Focus on thyroid categorically misses all the other radiogenic diseases. Poor rural populations currently under serviced by health care providers and residents that have no health care insurance will only get that care via a Congressional funding bill.

The environmental monitoring data collected by the Public Health Service for the Atomic Energy Commission and the Department of Energy must be declassified and released to the public using a similar process used for the Human Radiation Experiments. Department of Energy and Department of Defense continue to deny Freedom of Information Act requests for radioactive release documents on the grounds that national security will be compromised. No credible claim to national security can be made on 40 - 50 year old radioactive release data. A healthy democracy can not exist when the government hides its misdeeds behind a veil of secrecy.

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[6] NCI Study on I-131 Exposure from Nuclear Testing: A Preliminary Critique, David Rush, MD., H. Jack Geiger, MD. Physicians for Social Responsibility, Winter 1997-98 Health Research Bulletin

ADVISORY COMMITTEE FOR ENERGY-RELATED EPIDEMIOLOGIC RESEARCH

Senate Permanent Subcommittee on Investigations

EXHIBIT # 10

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September 27, 1998

Tim Connor
Chairman
Subcommittee for Community Affairs

Senator Susan Collins, Chair
Senator John Glenn
Senate Governmental Affairs Committee
Subcommittee on Investigations
100 Russell Senate Office Building
Washington, D.C. 20510

Dear Senators Collins and Glenn:

On behalf of the Department of Human Services Advisory Committee for Energy-Related Epidemiologic Research, I would like to submit the following report with recommendations for the record attended to the hearing before the Subcommittee on September 16th. The attached report from the Advisory Committee was unanimously adopted by members in attendance at our meeting on September 24th. I thought it relevant to the issues the Governmental Affairs Committee has been looking into with respect to the conduct of radiation research and, specifically, the questions of how to proceed to address the continuing health risks to the American people from nuclear weapons test fallout originating at the Nevada Test Site.

I'm sure I join countless other Americans in thanking you for your interest in these questions.

Sincere regards,

RESOLUTION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ADVISORY COMMITTEE ON ENERGY-RELATED EPIDEMIOLOGIC RESEARCH WITH REGARD TO EXPOSURES OF THE AMERICAN PEOPLE TO FALLOUT FROM THE NEVADA TEST SITE

AS UNANIMOUSLY ADOPTED, SEPTEMBER 24, 1998

It is with the knowledge of the history and circumstances appended to this document that the Committee approaches its recommendations as to how the Department of Health and Human Services should respond to the October 1997 report from the National Cancer Institute. Because the Committee advises the Secretary on the research agenda and related public health activities, there is a limit to the scope of our recommendations. Given the breadth of this particular issue, however, we think it appropriate to frame our recommendations with the following findings.

FINDINGS

FINDING #1: FEDERAL EFFORTS TO ADDRESS THE PUBLIC HEALTH CONSEQUENCES OF NEVADA TEST SITE FALLOUT ARE STILL INADEQUATE.

Despite the good intentions represented by the Radiation Exposure Compensation Act of 1990 (RECA), as amended, federal efforts to address the continuing health risks of populations exposed to radiation from nuclear weapons testing and nuclear materials production activities are clearly inadequate. RECA is a limited monetary compensation effort that provides $50,000 payments to people who can show they lived in "designated affected areas" of Nevada, Utah, and Arizona during high fallout periods and who were subsequently diagnosed with one of 13 types of cancer associated with radiation exposures.[1] As the 1997 NCI report on iodine-131 exposures from NTS fallout makes clear, one didn't have to live in the designated areas of the southwest to be exposed to fallout at levels that substantially increased the risk for cancer. Nor is cancer the only disease for which people exposed to fallout are at greater risk.

FINDING #2: THE DIFFICULTIES IN IDENTIFYING SPECIFIC FALLOUT INJURIES DO NOT ABSOLVE THE FEDERAL GOVERNMENT OF ITS RESPONSIBILITY TO SHAPE A MEANINGFUL PUBLIC HEALTH RESPONSE.

Given the widespread nature of the fallout and the limitations of epidemiology when it comes to identifying specific cases of low-dose radiation injuries, there are inherent and formidable difficulties in locating the people whose cancers or other health problems are attributable to fallout exposures. Still, the difficulties in identifying individuals whose injuries are caused by fallout exposures does not absolve the federal government of its civil and moral responsibility to aid the injured. The general obligation of the Government to attend to the well-being of its citizens is, in this instance, profoundly enhanced by the facts that the Government is responsible for the exposures and for failing to give people the information necessary to avoid or minimize the risks imposed upon them.

It is not the role of this committee to make recommendations on the delivery of health care. Based on the above principle, however, we encourage the Secretary to work with the President and the Congress to:

a) Improve the nation's capability to better identify the people who've either been injured by radioactive fallout or who are at substantially greater risk for injury due to their exposures. And,

b) Take reasonable and prudent steps to enhance the diagnostic and other health care services available to those who've been affected or who are at appreciably greater risk for injuries due to their exposures.

FINDING #3: RESEARCH IS NOT A PUBLIC HEALTH RESPONSE.

The Committee will recommend additional research activities to supplement the information provided in the 1997 NCI report on iodine-131 in fallout. It is important for us to note, however, that research, by itself, is not a substitute for the assistance that many exposed people believe, with good reason, that the Government has a responsibility to provide.

FINDING #4: THE DELAYS IN SHARING IMPORTANT PUBLIC HEALTH INFORMATION ABOUT FALLOUT EXPOSURES HAVE REINFORCED PUBLIC CYNICISM TOWARD FEDERAL OFFICIALS.

Specifically with regard to the October 1997 NCI report on iodine-131 exposures, the Committee is still troubled by the unnecessary delays in sharing important information on exposures and risks with Congress and the public. The request from Congress for this study came nearly 15 years before it was completed. The record and the literature indicates that the data collection and analysis were essentially complete five years before the study was released to the public. While we respect the deliberative and administrative processes necessary to put together a report of this magnitude, those requirements should neither have prevented nor discouraged the communication of substantive information of clear public health importance to Congress and the American people. Regrettably, the delays in releasing the information that the NCI did finally share with the public in the last year have only reinforced the cynicism of many citizens and exposed communities. It increases the burden that many federal agencies share in trying to overcome the suspicion that the Government is still unwilling to squarely acknowledge the harm caused by past policies and to commit resources to assist those who may have been injured as a result.

RECOMMENDATIONS

RECOMMENDATION #1: FULFILL THE LEGISLATIVE INTENT OF PUBLIC LAW 97-414.

The Department of Health and Human Services should, without further delay, take actions that are necessary to fulfill the substantive intent of Public Law 97-414, Section 7 which Congress passed in January of 1983, more than 15 years ago. This section of PL 97-414, the "Orphan Drug Act," provided the statutory mandate for the 1997 NCI study on iodine-131 in fallout. There are two parts of Section 7 that apply to assessing the public health impacts of fallout from the Nevada Test Site (NTS). Section 7(a) contains the mandate for iodine-131 and includes stipulations for thyroid cancer risk estimates that were not provided in the October 1997 NCI report. Section 7(b) called for the development of radio-epidemiological tables that would be inclusive of all cancer types and allow the calculation of individual risks to all cancers from exposure. As a first step, the Committee recommends that DHHS evaluate and seek to clarify the levels of uncertainty in the estimation of thyroid and other radiation doses attributable to NTS fallout.* This leads to our second recommendation.

*The Committee expects that with respect to the range of biologically significant radionuclides broadcast by the NTS bomb tests that the calculations of individual doses and risks can (as directed in Public Law 97-414, Section 7) be provided to exposed individuals. The Committee further expects that such estimates can be calculated with appropriate subjective confidence intervals and that clear communication of the qualifications and explanations of the uncertainties will be provided with the individual dose estimates.

RECOMMENDATION #2: COMPLETE A COMPREHENSIVE DOSE RECONSTRUCTION PROJECT FOR NEVADA TEST SITE FALLOUT.

The Department of Health and Human Services should, without further delay, commit itself to extending the nationwide dose reconstruction data base and dose assessment formulas for Nevada Test Site fallout beyond iodine-131 to include all of the biologically significant radionuclides in nuclear weapons test fallout. The goal of this project should be to fulfill the Congressional intent of PL 97-414 Section 7 and provide the American people with the accessible means to calculate their full exposure (and consequent health risks) to Nevada Test Site fallout. Among the first steps in this process is a review of the methodology and data used by the NCI in producing the 1997 report dealing with iodine-131, and an examination of the Department of Energy's Offsite Radiation Exposure Review Project which examined fallout distribution in counties near the Nevada Test Site. Given the regrettable insularity and lack of public oversight of the NCI report on iodine-131 in fallout, the Committee recommends that special attention be given to the creation of an oversight committee. The selection and charter of this oversight committee should be under the general supervision and oversight of the ACERER and be modeled on the health effects subcommittees that are monitoring health research activities and providing input to HHS and ATSDR at various specific sites around the nation.

RECOMMENDATION #3: NOTIFY AMERICANS OF THE FACTORS THAT MIGHT HELP THEM TO DETERMINE WHETHER THEY RECEIVED SIGNIFICANT RADIATION DOSES FROM NTS FALLOUT.

The Department of Health and Human Services should, without further delay, initiate a program to provide notification to Americans who are known or expected to have received significant radiation doses as a result of their exposure to fallout from the Nevada Test Site. This notification effort should, among other things, make use of the physical, atmospheric and meteorological analysis developed in support of the NCI report on iodine-131 exposures and be further guided by other known factors (i.e. age, sex, diet) that would be expected to have a significant effect on exposure, dose, and risk. At a minimum, this notification effort should have a high probability of reaching those at greatest additional risk for cancer and other illnesses (e.g. hypothyroidism) as a result of their exposure to NTS fallout.[2] The Committee strongly encourages that multiple methods be considered to make initial notifications and that supplemental materials and processes be developed to handle subsequent inquiries (see Recommendations #4 & #6). To the extent practical, the notification process should make use of existing networks, relevant community-based organizations, and entities such as the health effects subcommittees organized to address health concerns at U.S. Department of Energy facilities. The implementation of this program should be guided and monitored by the advisory body addressed in Recommendation #2.

RECOMMENDATION #4: CREATE A PUBLIC AND HEALTH CARE PROVIDER INFORMATION SERVICE ON NEVADA TEST SITE EXPOSURES AND RESULTING PUBLIC HEALTH CONCERNS.

Concurrent with the development and implementation of the notification measures recommended above, the Committee strongly recommends the creation of a service, or network of services, that can provide information and education resources to those notified. While the Committee strongly believes the Government has a moral responsibility to notify those who are still at significant risk for injury because of their exposures to fallout, we also believe this notification should be done responsibly, with adequate backup to answer immediate questions and provide broader education resources as necessary. It is plausible, for example, that notification without access to additional information would unnecessarily heighten fears as to the likelihood of cancer and other diseases. At worst, it might even lead to unnecessary surgery (e.g. the removal of healthy thyroid glands).

The Committee notes that the orientation, services, and materials developed by the Hanford Health Information Network (HHIN) to serve people exposed to radiation emissions (principally iodine-131) from the Hanford nuclear facility in Washington state are a useful model for this purpose. While the nature and scope of this service should be guided by input from the advisory body referenced in Recommendation #2, we recommend that DHHS begin assessing the costs, feasibility, and possible deployment of such a service immediately so as to prevent any additional delays in the notification effort.

RECOMMENDATION #5: SUPPORT ARCHIVAL PROJECTS TO DOCUMENT EXPERIENCES OF EXPOSED PEOPLES

The Committee recommends that the Department of Health and Human Services lend its cooperation and support to archival and other projects devoted to recording and preserving the histories of peoples exposed to radiation from nuclear testing and nuclear weapons materials production. Archival projects can yield important information that helps to shed light on exposures and health effects (i.e. exposure pathways, disease incidences). But the main reason to support these projects is that they can help honor and, to some extent, help restore the dignity of those whose experiences were overlooked or routinely disputed by the Government as it pursued nuclear weapons production and testing.

RECOMMENDATION #6: FURTHER EVALUATE SCREENING OPPORTUNITIES FOR THYROID CANCER. IT IS URGENT, IN THE MEANTIME, TO EVALUATE THE ADVISABILITY AND FEASIBILITY OF SCREENING FOR OTHER (NONCANCEROUS) THYROID AND PARATHYROID DISEASES, WITH A PRIORITY TO EVALUATE THIS SERVICE FOR THOSE AT HIGHEST RISK DUE TO THEIR EXPOSURES.

INTRODUCTION TO RECOMMENDATION #6

The Committee notes with interest and concern the decision of the Institute of Medicine's Guidelines on Cancer Screening Committee not to encourage medical screening as part of the nation's response to the NCI study of iodine-131 exposures to the American people.

Notwithstanding the uncertainties about individual doses, the documentation of the widespread pattern of fallout and the magnitude of thyroid doses provided by the NCI study lends considerable weight to public appeals for a public health response. In evaluating whether and how to provide such a response, government decision makers cannot avoid the historical and ethical context of these appeals. Not only are the health risks considerable, but the Government--by failing to warn and protect people from fallout exposures--bears direct responsibility for the ensuing injuries, even if it cannot be held legally accountable for them.

On the other hand, it is clear that the most direct response to the most common health effect--medical screening to detect thyroid cancers--is fraught with its own set of practical and ethical problems. There are legitimate and unresolved questions as to whether early detection of thyroid cancers can measurably improve the survival rate in the screened population. These questions must be weighed alongside the concern that thyroid cancer screening inevitably invites a significant number of inconclusive biopsy results, some of which will, in turn, lead to complete or partial removals of thyroid glands. Although some fraction of these removals will prevent the occurrence of thyroid cancers (a small percentage of which will be fatal cancers), most removals will not improve the health of individuals and all removals run the risk for potentially serious surgical complications. In short, it is not clear that a thyroid cancer screening program can be implemented in a way that, on whole, results in more physical good than harm. Thus, while the NCI study may have strengthened the moral argument that the Government "owes" exposed citizens a public health response, thyroid cancer screening could be the wrong response.

The paradox on the issue of thyroid cancer screening does not, however, end there. Even though there is no simple way to resolve just what public health response the Government should provide (and to whom it should be provided) there is an overriding moral obligation to inform people who are at significantly greater risk because of their exposures. Although this notification is not the same as offering enrollment in a thyroid cancer screening program, it inescapably invites many of the same ethical concerns. If, upon notification, individuals seek medical exams in response to their concerns about thyroid cancer, they are entering into the same realm of circumstances that could lead to the same diagnostic uncertainties and difficult decisions that so complicate the decision about whether to formally offer thyroid cancer screening.*

*On this point it is noteworthy that some authoritative health organizations--the American Thyroid Association and the Hanford Health Information Network--already encourage neck examinations for people who are concerned about their possible exposure to radioactive iodine from atmospheric nuclear weapons testing or nuclear facility releases.

This is an important consideration. If government decision makers were to decide that thyroid cancer screening is appropriate for some subset of persons exposed to NTS radioiodine, it is clear that screening would require a carefully prepared screening protocol and a medical outcomes decision path that, to the extent possible, acquaints people and their physicians with the best available information about risks and choices. It therefore stands to reason that if the Government is to undertake (as it should) a major effort to notify people about their risks from radioactive iodine exposures, it should be prepared to educate those notified about the questions and issues that await if those individuals seek a neck exam, and if that exam (palpation and/or ultrasound) results in detection of one or more nodules.

The Committee also notes with concern that the interpretation of case studies and the reasoning offered by the IOM panel on the thyroid cancer screening issue is squarely at odds with that applied by the Agency for Toxic Substances and Disease Registry (ATSDR) in its July 1997 proposal for carrying out the Hanford Medical Monitoring Program (HMMP).

The Committee has not yet been able to fully evaluate the differences in the circumstances and reasoning as applied by the ATSDR at Hanford and by the IOM Committee to the Nevada Test Site exposures. We believe these differences warrant careful evaluation before final decisions are made about what medical screening responses are appropriate to address radioiodine exposures attributable to NTS fallout.

One of our major concerns, in the meantime, is that the IOM recommendations could be used as justification for further delays in funding the Hanford Medical Monitoring Plan. We do not believe that funding should be delayed. While the Committee members are concerned about the provisions and consequences of the Hanford Medical Monitoring Plan, we respect the process by which ATSDR brought together scientists, expert consultants, and a diverse group of stakeholders to shape the scope and details of the plan.

Coupled with the U.S. Department of Energy's resistance to providing timely and adequate funding for the HMMP, we are also concerned about the public perception that the Government may once again be backing away from its responsibility to extend public health services to those who received significant exposures from federal nuclear weapons production and testing activities. In this instance, the plan proposed by ATSDR was carefully developed in accordance with ATSDR's mandate under the federal Superfund law to provide health surveillance to exposed communities when a significant increased risk of health effects has been demonstrated.

Finally, the Committee also believes it important to recognize basic differences in the techniques and issues related to screening for thyroid cancer and screening for hypothyroidism. In screening for thyroid cancer, any expected benefits for early detection of cancers must be weighed against the inevitable harm of instigating a certain number of unnecessary surgeries. This difficult trade-off should not, however, cloud the issue when it comes to making decisions about whether and how to implement screening for hypothyroidism. Because screening for hypothyroidism involves blood tests rather than direct examination of the thyroid by palpation, ultrasound and fine needle aspiration biopsy, and because treatment for hypothyroidism does not involve surgery, a hypothyroidism screening program can be implemented with a greatly diminished risk for promoting unnecessary surgery. Because undiagnosed hypothyroidism can be a seriously debilitating and sometimes lethal condition, and because the number of diagnoses and referrals for treatment could be substantial, the Committee believes it is important to evaluate screening for hypothyroidism separately from the evaluation of whether and when to implement screening for thyroid cancer.[3]

6) DHHS should carefully evaluate the recommendations of the National Research Council's Review of the National Cancer Institute's Report on Exposure of the American People to I-131 from the Nevada Test Site with regard to screening for thyroid cancer and other thyroid diseases. In light of the IOM Committee's recommendations, and the substantive concerns about the negative consequences of implementing a large-scale screening program, the Committee recommends that DHHS look carefully at opportunities to implement screening efforts under circumstances that can reasonably be expected to promote more benefit than harm to those for whom the program would be available. In particular, we recommend DHHS independently evaluate the cost, feasibility, and expected outcomes of implementing screening programs for thyroid cancer and hypothyroidism.

With regard to screening for thyroid cancer, the Committee respects the reasoning that discourages moving forward quickly with a general thyroid cancer screening program. It is conceivable, however, that the anticipated harm to benefit ratio (namely, the number of unnecessary thyroid removals versus the number of confirmed thyroid cancers) could be significantly different among one or more subpopulations who received higher doses.

For this reason, we recommend that DHHS move with deliberate speed to evaluate the opportunities for, and feasibility of, identifying and locating high dose subpopulations for whom thyroid cancer screening would merit further consideration. In evaluating such subpopulation(s) for thyroid cancer screening, the Committee further recommends that protocols for identification and implementation address the following considerations:

a) dose
b) gender
c) genetic predisposition, including ethnicity
d) limited and discriminate use of ultra-sound
e) limited and discriminate use of biopsy (fine needle aspiration)
f) quality assurance
g) informed consent for followup surgeries

With respect to screening for hypothyroidism, the Committee recommends a much more proactive approach. On this subject, the key considerations are those of cost, quality, and post-diagnosis protocols for referral. In implementing screening for hypothyroidism, the Committee recommends that DHHS develop strategies to help ensure that those at highest risk for hypothyroidism have the earliest access to screening.

Finally, the Committee recommends that further evaluation of thyroid screening be done under the oversight and with the participation of the advisory body referenced in Recommendation #2. This advisory body should have an opportunity to make its own recommendations to the Secretary with respect to the feasibility and advisability of implementing screening programs.

The commitee also draws attention to the fact that the full implementation of any screening and/or treatment programs will be seriously impaired by the unaddressed problems of the millions of exposed persons who lack health insurance, other means to pay for care, reasonable access to physicians, or al of these. If such plans are to be feasible, this issue should not continue to be ignored. If such plans are to be equitable, the government must assume responsibility for providing access to care and/or the costs of such care for those exposed persons who lack such access or the means to pay for it.

HISTORY AND BACKGROUND FOR THESE RECOMMENDATIONS

Beginning with the war-time "Manhattan Project" in 1942, the U.S. Government opened a new chapter in human history. The scientific and technological feats that brought in the Atomic Age are as profound as the disquieting questions that followed, questions about how and whether societies can make use of nuclear technology while exercising the wisdom and restraint it so clearly requires.

There is, however, an important part of this history for Americans that is best informed by the experience of citizens who live downwind from the Nevada Test Site (NTS), the 1,350 square mile outpost in the seemingly isolated desert of southern Nevada. These were the people who, especially during the peak period (1951 thru 1958) of above ground nuclear testing at NTS, found themselves in harm's way from radioactive fallout.

The hazard was physical in nature. Fallout particles drifted and rained down from the sky to irradiate on contact, to be inhaled, and to be ingested in water, milk, and foodstuffs. Today, the best scientific evidence supports the conclusion that the delayed effects of radioactive fallout were likely harmful to tens, if not hundreds, of thousands of people. Because of the latency between exposure and the onset of cancer and other diseases, the risks for these injuries continue to this day.

What the October 1997 National Cancer Institute report on radioactive iodine-131 exposures makes clear is that the hazards from weapons test fallout at NTS were *not* confined to Nevada, Utah, and Arizona. People--and especially young children--living downwind of the test site from Idaho to Texas, and in between, all the way to the eastern seaboard, were likely to have received significant radiation doses if they were drinking milk from cows or goats pastured in areas where the radioactive debris from bomb tests rained out in high concentrations.

As advisors to the U.S. Department of Health and Human Services responsible for making recommendations on how federal public health agencies should respond to information like that provided in the NCI report, we believe we have a two-fold obligation. To Secretary Shalala we owe our best efforts to make recommendations that will advance scientific knowledge about radiation effects and respond to legitimate occupational and public concerns about past and continuing exposures. To the American public we owe a basic commitment to understand the experiences of exposed communities and to be attentive to the legitimate expectations of these communities for honest and accurate information.

It is with these obligations in mind that we give our attention to the issues our nation still confronts with respect to the public health legacy of nuclear weapons testing. The testimonies and historical evidence brought before Congress and the courts over the past 40 years convey a deeply troubling story, one that is all the more disturbing because it took place in the world's oldest democracy. The record is clear that, at a minimum, officials of the U.S. Atomic Energy Commission (AEC) actively discouraged the dissemination of important information about radioactive fallout for fear that public concerns about health consequences would undermine public acceptance of nuclear weapons testing.

This history from the perspective of the "downwinders" is not just the history of delayed injury. It is also the history of being made nearly invisible. It is hard to "see" the injuries caused by radioactive fallout because even though the weight of science informs us that the injuries are numerous, serious and real, they can only be "detected" or "observed" in carefully constructed health studies. Because of the limits of health science, we are all but forced to see radiation injuries as anonymous statistics rather than in the faces and lives of those who are actually affected.

But the main reason for the near invisibility of the downwinders has little to do with the limits of science. Rather, it has to do with the unwritten but clear policy of neglect and isolation inflicted on them by their own government by its failure to warn and protect people from radioactive fallout.

Because the AEC spokesprson failed to acknowledge the nature and extent of health risks imposed on exposed people, some citizens filed claims in federal court. In these court cases, the Justice Department's position (in defense of the Atomic Energy Commission) was to strongly resist not just the specific claims of individual plaintiffs but the science that provided the general basis for the claims.[4]

Rather than committing itself to a conscientious policy, the Government reacted in ways that perpetrated a serious injustice against a large number of its citizens. Only with the Radiation Exposure Compensation Act of 1990 (RECA) did Congress and the Administration finally take a limited step to make amends with an important but relatively small portion of those citizens who were put at greatest risk.

Much of what is disturbing about this experience is what it has done to public attitudes about scientists who work for and with government agencies involved with nuclear energy and the deep public skepticism toward their scientific work and statements. In trying to assuage public concerns about fallout, the then-Atomic Energy Commission essentially reversed the precautionary public health ethic of erring on the side of public protection.

Although more is known today about the health effects of low dose radiation than was known in 1951, there were clear indications from the earliest days of the testing program that radioactive fallout would put scores of people at greater risk for cancer and other diseases.[5] This information should have been used to inform and protect the public. It wasn't. Instead, as part of the public relations shield for the nuclear testing program, the science was distorted by government spokespersons to promote doubt about radiation hazards.

Among the regrettable historical facts that the Committee must acknowledge in addressing this issue is that during the 1950s officials of the U.S. Public Health Service were sometimes prohibited from communicating directly and freely to the American people about the risks posed by nuclear fallout.[6]

This document is hereby forewarded to the full ACERER for its consideration and action.

Footnotes

1) The Radiation Exposure Compensation Act (RECA) also provides monetary compensation for uranium miners who were exposed to high levels of radon between 1947 and 1971 working in mines in Colorado, Utah, New Mexico or Arizona and who've since developed lung cancer or three other lung diseases. Eligibility for both sets of claims--from NTS exposure and mining exposures--is limited to those who filed claims within six years after enactment of the legislation.

2) The ACERER recommendation on notification is consistent with the recent conclusions of the National Academy of Sciences/Institute of Medicine Committees that reviewed the National Cancer Institute report. The NAS/IOM recommendation reads, in part: "Although most in the population have not been significantly affected, those that have been affected, mainly be virtule of their life style and birth date, should be appropriately informed." (p.68 of pre-publication report).

3) The Agency for Toxic Substances and Disease Registry (ATSDR) predicts that if 6,000 eligible participants are enrolled for the first round of screening under the Hanford Medical Monitoring Program that 45 cases of previously undiagnosed hypothyroidism will be detected. In follow up communication with the Committee, ATSDR reports that the projected number of cases is conservative because it is projected based on the expected rate of hypothyroidism found in a similar but unexposed population. Thus, although the literature on radiation-induced autoimmune thyroiditis (resulting in hypothyroidism) indicates that a substantial number of people eligible for the HMMP have received thyroid doses from radioactive iodine sufficient to increase their risk for auto-immune induced hypothyroidism, ATSDR has not yet provided an estimate of the additional cases it expects based on the radioiodine exposures.

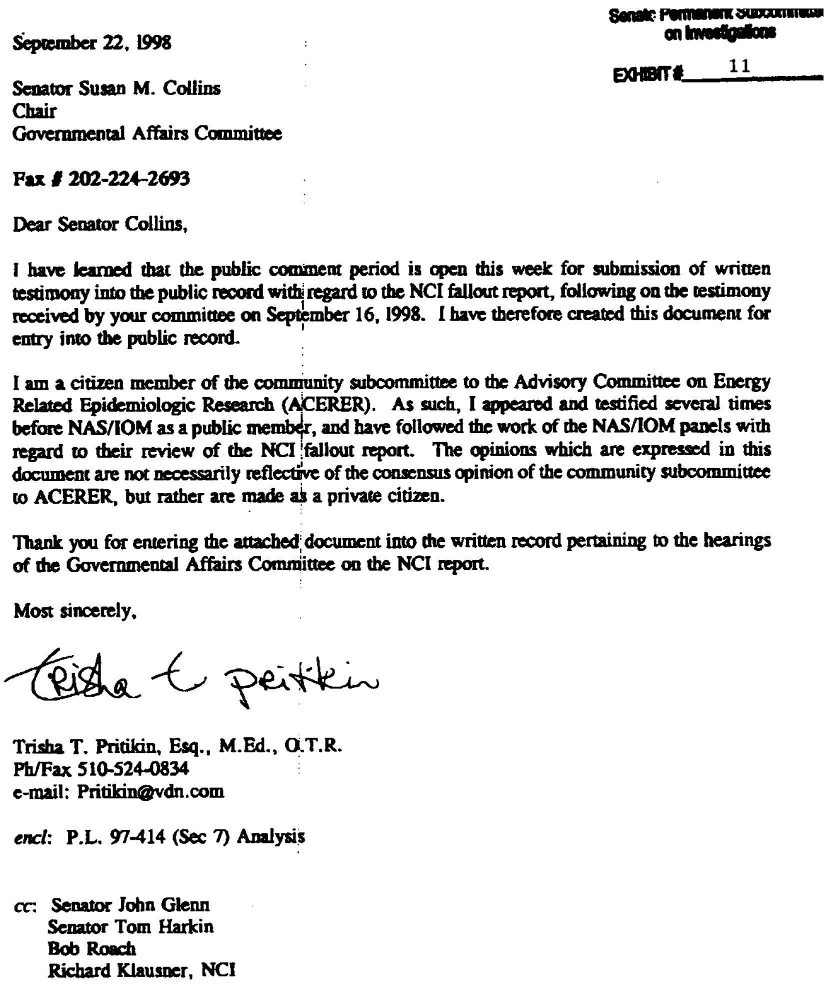
The committee recognizes and commends the ATSDR process for the way in which it solicited and integrated stakeholder perspectives on benefits, harms, and how to weigh and balance them.

4) As its primary defense against radiation injury claims from those exposed to releases from nuclear materials production or weapons testing operations, the government still asserts sovereign immunity under the Federal Tort Claims Act. The government has argued, successfully, that under the FTCA even decisions about whether to warn downwind populations are within its "discretionary" powers. This legal defense, by itself, raises profound questions for a democracy, questions that the Administration and Congress must continue to grapple with if they are sincere about wishing to correct past injustices and avoid future such cases. Still, the government's sovereign immunity defense has not diminished the intensity with which the Justice Department strives to impeach the credibility of plaintiffs and scientists willing to provide testimony in support of plaintiffs.

5) One of the earliest acknowledgements of the threats posed by testing to people downwind was presented in an October 9, 1946 memo from Colonel Stafford Warren, the officer in charge of radiological safety at the Operation Crossroads nuclear tests in the Pacific. In this memo, addressed to General Leslie Groves, Col. Warren states that radioactive fragments from exploded nuclear bombs will "in extremely small amounts deposited in the marrow will eventually cause progressive anemia and death years later." Further, the material "mixed with these fission products, beta and gamma emitters, is an insidious hazard--not immediately dangerous but if absorbed into the body it produces a long time hazard...The amount necessary to cause this hazard is minute--measured in millionths of a gram. The harmful effects occur years later..I believe a frank statement of this sort should be made now to professional and intelligent lay groups as part of the general discussion in the effect of the bomb as a whole." In his 1986 book, *Justice Downwind, America's Atom Testing Program in the 1950s*, University of Utah Professor Howard Ball reports that this memo was part of the documentation cited by the U.S. Department of Justice in Federal District Court in California (*Alice P. Broudy v. United States, et al.*) to support its contention--as part of a sovereign immunity defense--that "government officials and scientists were aware of the hazards of radiation since the inception of the nuclear weapons programs...specifically that fallout could cause cancer."

After reviewing extensive Atomic Energy Commission records as part of a 1979 investigation, the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce concluded that prior to tests at the Nevada Test Site the government had ample information to show that people downwind required protection. However, the Subcommittee reported, "all evidence suggesting that radiation was having harmful effects, be it on sheep or on people, was not only disregarded but actually suppressed."

6) U.S. Congress, House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, and Senate Labor and Human Resources Committee, Health and Scientific Research Subcommittee, and the Committee on the Judiciary, *Health Effects of Low-level Radiation, Vol. 1,* p. 221 96th Congress, 1979. {As reported in Caufield, Catherine; *Multiple Exposures, Chronicles of the Radiation Age*, p. 118, Martin Secker & Warburg, Ltd, 1989.} See, also, Ball, Howard, *Justice Downwind, America's Atomic Testing Program in the 1950s*, pp. 43-48, p. 109. See, also, Fuller, John G.; *The Day we Bombed Utah*, NAL Books, 1984, p. 171-180. See, also, Wasserman, Solomon, Alvarez, Walters; *Killing Our Own* , Delacorte Press, 1982, p. 114.



Senate Permanent Subcommittee
on Investigations

EXHIBIT # 11

September 22, 1998

Senator Susan M. Collins
Chair
Governmental Affairs Committee

Fax # 202-224-2693

Dear Senator Collins,

I have learned that the public comment period is open this week for submission of written testimony into the public record with regard to the NCI fallout report, following on the testimony received by your committee on September 16, 1998. I have therefore created this document for entry into the public record.

I am a citizen member of the community subcommittee to the Advisory Committee on Energy Related Epidemiologic Research (ACERER). As such, I appeared and testified several times before NAS/IOM as a public member, and have followed the work of the NAS/IOM panels with regard to their review of the NCI fallout report. The opinions which are expressed in this document are not necessarily reflective of the consensus opinion of the community subcommittee to ACERER, but rather are made as a private citizen.

Thank you for entering the attached document into the written record pertaining to the hearings of the Governmental Affairs Committee on the NCI report.

Most sincerely,

Trisha t pritkin

Trisha T. Pritikin, Esq., M.Ed., O.T.R.
Ph/Fax 510-524-0834
e-mail: Pritikin@vdn.com

encl: P.L. 97-414 (Sec 7) Analysis

cc: Senator John Glenn
Senator Tom Harkin
Bob Roach
Richard Klausner, NCI

Public Comment
Governmental Affairs Committee
Hearings with regard to the NCI Fallout Study

To: Senator Susan M. Collins
Chair
Governmental Affairs Committee

Please enter the following into the written record:

I am a person substantially exposed, as an infant and child, to radiation emissions from the Hanford nuclear weapons facility and to fallout from the Nevada Test Site bomb tests during the 1950s. I would like to make several comments for the record as to the role of Mr. Bruce Wacholz with regard to the NCI fallout study, and in regard to avoidance of potential conflict of interest in follow-up work required within the mandate of Section 7 of Public Law 97-414, the triggering legislation for the NCI study.

I. PERSONAL RESPONSE TO COMMENTS BY BRUCE WACHOLZ

I would like to comment on a statement by Bruce Wacholz, chief of the radiation effects branch of the NCI who coordinated the fallout study, made during the testimony taken before the Senate Governmental Affairs Committee, on September 16, 1998:

> **Mr. Wacholz:** (regarding the many years of delay in making public the results of the NCI fallout study): *"The sense was that nobody was really terribly interested in this."*
>
> **My response to Mr. Wacholz's comment:**
>
> As so aptly stated by Senator Susan Collins (R-Maine), Chair, Senate Governmental Affairs Committee,: *"The public couldn't be interested in what the public didn't know."*
>
> For all of those people significantly exposed to fallout from NTS bomb tests, this is the ***third major human rights violation*** we have endured:
>
> 1. First, in our involuntary exposure, many of us during infancy and childhood when we were most vulnerable to these exposures;
>
> 2. Then, through the years of suffering with the health impacts of these unknowing exposures (decades of untreated, severe hypothyroidism, or worse);

3. And now, in having withheld from us the results of the NCI fallout report (including individual dose and risk estimates due to our exposures) for so many years.

I question whether the NCI report would ever have been released by the NCI, had portions of the report not been leaked to the media.

Mr. Wacholz's comment indicates, in my mind, what appears to be his own personal disregard for the welfare of those significantly impacted by NTS fallout. I know firsthand what such disregard can cause. I myself suffered for decades with severe untreated hypothyroidism, the result of exposure to radioiodine emissions from the Hanford nuclear facility, because Hanford officials did not make these exposures public knowledge until 1986, almost *four decades* after my exposures began. This neglect to inform also played a major role in the death of my father (exposed to radioiodine emissions from Hanford and the Nevada Test Site) from thyroid cancer, a cancer which could have been diagnosed much earlier, before it spread to other parts of his body and killed him, had Hanford officials only informed those of us so exposed at a much earlier time so that we could seek appropriate diagnosis and treatment.

How then can further potential conflict of interest be avoided in the work still needing to be done in follow-up to the NCI fallout study?

II. FOLLOW-UP TO NCI REPORT: AVOIDANCE OF FURTHER CONFLICT OF INTEREST

Bruce Wacholz's clear conflict of interest, as former AEC official moving to lead the NCI study of the public health impact of NTS bomb test fallout, has been discussed widely throughout the media and within congressional hearings conducted by the Senate Governmental Affairs Committee, held September 16, 1998.

The issue then becomes avoidance of future such conflict of interest situations within follow-up work to the NCI study. Follow-up work required includes:

1. Calculation of individual risk and dose from the other biologically significant radionuclides released from NTS bomb tests, as stipulated by P.L. 97-414 (Sec. 7)[1].

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[1] See Analysis of P.L. 97-414 (Sec. 7), attached.

2. Updating of probability of causation tables as required under Section 7 of P.L. 97-414.

3. Initiation of public information programs in order to inform those exposed as to the potential health outcomes which may have, or may in the future, result from NTS exposures. This would include revision of the NCI website to make it understandable to the public.

4. Evaluation of the feasibility of development of a medical screening program for thyroid cancer and thyroid disease, targeting a highest risk subgroup of those exposed to radioiodine from NTS fallout.

Recommendations: Through appropriate congressional action, the lead on these and related tasks to be completed in follow-up to the NCI fallout report should be given over to the Centers for Disease Control and Prevention, with its proven history of concern for public health. All such work should be subject to independent oversight, such as through the Advisory Committee on Energy Related Epidemiologic Research (ACERER), the membership of which includes public representation. A community subcommittee is additionally in place in an advisory capacity to ACERER.

III. FUNDING FOR PUBLIC HEALTH ACTIVITIES MUST NO LONGER FLOW THROUGH DOE

We must learn an important lesson from all of this. First of all, radiation health studies must NOT remain within the control, either budgetary or otherwise, of the Department of Energy. This is, in essence, putting the "fox in charge of the chicken coop".

Those with past professional involvement with management of AEC, or with past or present involvement with the management of DOE, must not have undue influence over studies of the public health impact, or worker health impact, of the activities of the AEC or DOE. This is a very simple premise and a very important one.

Finally, funding of public health activities relating to radiation exposure must not be at the whim of the Department of Energy. Independent line items must be appropriated and earmarked directly to the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, the National Institute of Occupational Safety and Health (NIOSH) and related agencies of the Public Health Service, rather than appearing within the Department of Energy's budget, to be allocated or not allocated by the Department of Energy in accordance with the whim of its current decision makers charged with budgetary matters, whether on a headquarters or field office level.

Thank you for this opportunity to enter my comments as a private citizen into the public record.

Sincerely,

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7/31/98
Trisha T. Pritikin
P.L. 97-414 (SEC. 7)

SECTION 7 OF PUBLIC LAW 97-414 REQUIRES INDIVIDUAL DOSE AND RISK ESTIMATES FOR I-131 AND ALL OTHER RADIONUCLIDES FROM ATOMIC BOMB TESTS

I. SUMMARY OF SECTION 7:

Public Law 97-414 [hereinafter referred to as P.L. 97-414], the "Orphan Drug Act," was enacted on January 4, 1983. Section 7 of P.L. 97-414 *(96 Stat. 2059; see 42 USC 241 note)*, originated as an amendment introduced by Senator Orrin G. Hatch (R-UT).[1] The intent of Section 7 of this law is to assess the public health impact of Nevada Test Site atomic weapons testing.

Section 7 has two subparts, (a) and (b): Section (a) specifically addresses I-131 and thyroid cancer, while Section (b) addresses the multitude of radiogenic cancers and their individual probability of causation based upon exposure to all the radionuclides from atomic bomb tests.

SEC. 7(a): I-131: AN INDIVIDUAL'S RISK OF THYROID CANCER

Sec. 7(a) requires the Secretary of Health and Human Services to estimate the doses of I-131 received by the American public from atomic bomb tests. Further, this section requires that risks of thyroid cancer to individuals based upon the dose these individuals received of I-131 be calculated. This is clearly a stipulation that individual risk of developing thyroid cancer due to a person's estimated dose of I-131 be provided, not just excess numbers of cancers estimated in the overall population.

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[1] The Orphan Drug Act (H.R. 5238) amends the Federal Food, Drug, and Cosmetic Act, the Public Health Services Act, and the Internal Revenue Code to facilitate the development of drugs for rare diseases and conditions, and for other purposes. Section 7 of P.L. 97-414 addresses the public health impact of Nevada Test Site atomic weapons testing.

SEC. 7(b): OTHER RADIONUCLIDES: AN INDIVIDUAL'S RISK OF DEVELOPING ANY OF THE RADIATION-RELATED CANCERS FROM EXPOSURE TO THE OTHER RADIONUCLIDES EMITTED FROM ATOMIC BOMB TESTS:

Sec. 7(b) expands the scope of the mandate beyond analysis of individual risk due to exposure to I-131, which was only one of the radioactive substances released during the bomb tests.

Under Section 7(b), radioepidemiological tables are to be devised and published in order to provide individuals with probability of causation of developing *any* of the radiogenic cancers which may be related to exposure to the radioactive substances emitted from the atomic bomb tests, based upon the specific estimated doses of each of these substances, from 1 millirad to 1000 rads. Further, in order to provide *individual risk estimates*, an individual's specific risk factors (sex, age at time of exposure, time from exposure to the onset of the cancer in question, and related individual risk factors) for the specific doses of these radionuclides must be provided.

Further, for each individual, the probability of causation for each cancer, based upon exposure to each radionuclide, is to be calculated and displayed as a single percentage figure. And, for each cancer, the credibility, validity, and degree of certainty (uncertainty range) of the calculation of probability of causation, is to be provided.

Formulas upon which probability of causation is calculated for each cancer are to be published along with these calculations.

II. SECTION 7 OF PUBLIC LAW 97-414:

The full text of Section 7 of P.L. 97-414 follows:

> "*Sec. 7. (a)* In carrying out section 301 of the Public Health Service Act, the Secretary of Health and Human Services shall-
>
> *(1)* conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;
>
> *(2)* conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

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(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

(4) prepare and transmit to the Congress within one year after the date of enactment of this Act a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

(b)(1) Within one year after the date of enactment of this Act, the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had *any of the radiation related cancers* and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a *probability of causation* of developing *each radiation related cancer* with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish-

> **(A) for the tables of *each radiation related cancer*, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and**
>
> **(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.**

(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the

> United States, and shall be devised in accordance with the best available scientific procedures and expertise. The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise." [Emphasis added]

The highlighted portions of the text of Section 7(b) show that the intent is clearly that of assessing for each individual exposed, the health impact of exposure to *all of the radionuclides* emitted from Nevada Test Site atomic bomb tests, not merely the effect of I-131 exposure on development of thyroid cancer. This is made clear by the fact that, whereas Sec.7(a) refers only to thyroid cancer, Sec.7 (b) refers only to "*each radiation related cancer*" and "*any of the radiation related cancers*," without mentioning thyroid cancer at all. Clearly, had the Legislature intended Sec. 7(b) to be limited to thyroid cancer, it would have so indicated by using the specific term "thyroid cancer" in Section 7(b).

By using only the term "thyroid cancer" in Sec. 7(a), and using the phrases "each radiation related cancer" and "any of the radiation related cancers" in Sec. 7(b), Congress demonstrated that it meant something different. Moreover, the phrases "each radiation related cancer" and "any of the radiation related cancers," are plainly references to more than one cancer and therefore cannot reasonably be read as a reference to a single radiation-related cancer, thyroid cancer.

III. LEGISLATIVE INTENT OF SECTION 7 OF P.L. 97-414

The legislative intent of Sec. 7 of P.L. 97-414, as evidenced by its legislative history, would be relevant to determine the meaning of Sec. 7 in the event that the wording of the statute were deemed to be ambiguous. Although the statutory language is, in fact, clear and unambiguous, the fact is that if legislative history were found to be relevant, an examination of that history plainly demonstrates that Sec. 7 was intended to mandate assessment of individual dose and risk for *all* radiogenic cancers which may be caused by exposure to any of the radioactive substances released from the Nevada Test Site bomb tests.

Sec. 7 was introduced as an amendment to P.L. 97-414 by Senator Orrin G. Hatch:

> "[Section 7 of P.L. 97-414] *directs the Department of Health and Human Services to conduct two activities important to gaining a better understanding of the health effects of radioactive fallout from above-ground testing of nuclear weapons.*
>
> *The first requirement is to develop 'radioepidemiological tables' which catalog for each [illegible]ogenic cancer the probability that a given d[illegible] radiation ca[illegible] the cancer of a victim who has received [illegible] dose.*
>
> *The second requirement is to investigate relationship between iodine 131 and thyroid cancer in light of the [illegible]on in the environment of iodine 131 as a product of nuclear* [illegible]asis added].

Senator Edward Kennedy, in support of passage of Section 7 of P.L. 97-414, again emphasized the two separate areas of concern defined within Section 7: (a) the relationship between thyroid cancer and I-131, and (b) the causal relationship between all the radionuclides (e.g., *all* low-level ionizing radiation) emitted from atomic bomb tests and the other cancers caused by an individual's exposure to these other radionuclides:

> "*...[this] legislation would require the Department of Health and Human Services to conduct studies of the health effects of iodine 131 and low level ionizing radiation. For several years I have worked to enact legislation establishing a compensation system for American citizens exposed to radiation as a result of open air atomic bomb testing during the 1950's at the Nevada Test Site. One of the roadblocks to our achieving this important legislation is our lack of complete understanding of the relationship between iodine 131 and thyroid cancer and the causal relationship between exposure to low level ionizing radiation and cancers.*"[3] [Emphasis added]

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[2] 128 CONG REC 26975-76, 31622-23 [1982].

[3] 128 CONG REC 26978 [1982].

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IV. P.L. 97-414 (SEC. 7): SUMMARY OF CONCLUSIONS

I. BOTH THE PLAIN LANGUAGE OF SECTION 7 of P.L. 97-414 AND A REVIEW OF THE CONGRESSIONAL INTENT OF THIS LEGISLATION CLEARLY SHOW THAT SEC. 7 OF P.L. 97-414 REQUIRES BOTH:

(A) A STUDY OF THE CAUSAL RELATIONSHIP BETWEEN I-131 AND THYROID CANCER (INCLUDING INDIVIDUAL DOSE AND RISK ESTIMATES); AND

(B) INDIVIDUAL DOSE AND RISK ESTIMATES INDICATING PROBABILITY OF CAUSATION OF ALL RADIATION RELATED CANCERS DUE TO EXPOSURE TO ALL RADIONUCLIDES EMITTED FROM THE NEVADA TEST SITE BOMB TESTS FOR DOSES RANGING FROM 1 MILLIRAD TO 1000 RADS.

II. THE FOLLOWING ACTIVITIES, WHICH WERE MANDATED *FIFTEEN YEARS AGO* BY THIS LEGISLATION MUST BE CARRIED OUT, WITH PUBLIC PROCESS AND OVERSIGHT, WITHOUT DELAY:

(A) CALCULATION OF INDIVIDUAL DOSE AND RISK ESTIMATES RELATING TO INDIVIDUALS' EXPOSURE TO I-131 FROM ATOMIC BOMB TEST FALLOUT

(B) CALCULATION OF INDIVIDUAL DOSE AND RISK ESTIMATES FOR EXPOSURE TO RADIONUCLIDES OTHER THAN IODINE-131 EMITTED FROM NEVADA TEST SITE BOMB TESTS

(C) PUBLICATION OF UPDATED RADIOEPIDEMIOLOGICAL TABLES THAT ESTIMATE THE LIKELIHOOD THAT PERSONS WHO HAVE OR HAVE HAD ANY OF THE RADIATION RELATED CANCERS AND WHO HAVE RECEIVED SPECIFIC DOSES PRIOR TO THE ONSET OF SUCH DISEASE DEVELOPED CANCER AS A RESULT OF THESE DOSES

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 12

Health & Energy Institute
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Takoma Park, MD 20912
U.S.A.
Phone: 301-585-5831

October 1, 1998

Senator Susan Collins
Attn: Mary Robertson
100 Senate Russell Bldg.
U. S. Capitol
Washington, DC 20010

Dear Senator Collins:

Thank you for sponsoring the hearing held September 14, 1998 on the NCI study of radiation fallout over the United States which I had the opportunity to attend. During the hearing questions were asked regarding why the National Cancer Institute was asked to conduct their study. I worked with a variety of organizations and individuals over the past decades who sought the information that NCI failed to disclose. I am enclosing a copy of the Radiation Victims Bill of Rights, which has been signed or endorsed by an extensive lists of organizations and individuals. Many of these same folks endorsed the First Global Radiation Victims Conference held in New York City in 1987, a list of whom are enclosed.

I drafted testimony for myself and E. Cooper Brown, Esq., President of the National Committee for Radiation Victims that was presented before the Senate Committee on Labor and Human Resources June 12, 1985 and that addresses some of the concerns of your own panel, so I am enclosing a copy. If any of this information can be included in the record, there may be members of the public who will find it useful.

Thank you again for holding these important hearings. I would like to receive a copy of the hearings when they are published, and I would be happy to assist you in any way.

Cordially,

Kathleen M. Tucker

Kathleen M. Tucker, Esq.
President, Health & Energy Institute

KT:mag

Enclosures

HEALTH & ENERGY INSTITUTE

Radiation Victims Bill of Rights

Preamble

WHEREAS millions of people have been and are currently exposed to ionizing radiation—on the job, in military service, as medical patients and as medical personnel, in communities near or downwind from testing sites, uranium mines, mills, or tailings piles, in the area of reactors, weapons plants, waste sites, and other nuclear facilities,

AND WHEREAS they and their children now suffer or risk an array of radiation-induced injuries ranging from acute radiation syndrome to cancers, leukemias, diseases of the immune system, blood diseases, psychological disorders, reproductive impairment, and genetic diseases in current and succeeding generations,

AND WHEREAS radiation victims also suffer from an abrogation of their rights due to needless exposure, biased research, purposeful misinformation, lack of sound medical care, and denial of compensation for injuries received,

BE IT RESOLVED THAT to defend human health, to protect our genetic heritage, and to stem the erosion of citizens' rights, we adopt this **Radiation Victims' Bill of Rights:**

RADIATION VICTIMS HAVE THE RIGHT TO:

I. PREVENTION OF NEEDLESS EXPOSURE TO RADIATION

II. HONEST RESEARCH ON HEALTH EFFECTS OF RADIATION

III. FULL DISCLOSURE OF RADIATION RECORDS AND RADIATION HAZARDS

IV. COMPETENT MEDICAL CARE FOR RADIATION INJURIES

V. FINANCIAL COMPENSATION FOR RADIATION INJURIES

I. Prevention of Needless Exposure to Radiation

A. All people have the right to freedom from needless exposure in their workplaces or communities, and the right to refuse hazardous work or medical treatment.

B. People have the right to the best available means of radiation protection, including, for all radiation workers, the possession of monitoring devices that signal the presence of radioactivity as it occurs, rather than those that merely indicate afterwards that an exposure has already taken place.

C. Radiation workers have the right to the same legal and administrative protections available to other workers in hazardous industries, and those individuals who report problems have the right to safeguards for their lives and careers.

D. People have the right to independent regulation of the radiation industry.

E. Radiation victims have the right to full participation in establishing "acceptable" standards and "allowable" limits for radiation exposure.

II. Honest Research on Health Effects of Radiation

A. People have the right to have public funding for research on radiation health effects transferred from agencies with nuclear promotion mandates to agencies with public health mandates.

B. People have the right to have public funds set aside for the study of the pathways of radiation through the air, soil, water and the food chain.

C. Health research professionals have the right to be granted access to raw research data for studies used to determine radiation exposure standards such as data on atomic bomb survivors or workers at federal nuclear facilities.

D. Representatives of victims organizations have the right to serve on review committees for radiation effects research funded by the government.

E. Radiation victims have the right to a national tumor and mortality registry accessible to all upon request.

F. Radiation workers have the right to a national radiation registry.

III. Full Disclosure of Radiation Records and Radiation Hazards

A. Individuals have the right to receive comprehensive personal exposure records in clear, understandable language, or a clear statement that no such records were made or still exist for that individual.

B. Unions, victims' organizations, health agencies and other representative groups have the right to complete radiation exposure monitoring, and medical information, free of charge.

C. People have the right to accurate information and education about the physical, reproductive, and psychological effects of radiation exposure.

D. Workers have the right to be informed in advance of all radiation hazards, potential radiation hazards and hazardous materials used in the workplace.

E. People have the right to disclosure of all data regarding radiation releases of any of the nearly 500 radioactive isotopes that may be released into the workplace or the environment.

IV. Competent Medical Care for Radiation Injuries

A. All people have the right to the best available medical treatment for radiation-related diseases.

B. All radiation victims have the right to choose their health care providers or personal physicians.

C. All radiation victims, including soldiers exposed at atomic test sites, the people living near atomic test sites, nuclear facilities, or other radioactive sites, as well as the workers at those sites and facilities, have the right to appropriate screening and screening facilities in order to detect radiation-related diseases as early as possible.

D. All radiation victims have the right to representation on panels establishing or reviewing radiation screening programs.

V. Financial Compensation for Radiation Injuries

A. All radiation victims have the right to adequate compensation for physical injury, reproductive impairment and psychological distress.

B. States, counties, and localities have the right to expand compensation protections for radiation victims.

C. All individuals with documented radiation exposures or symptoms demonstrating radiation exposure have the right to legal "presumption of causation."

D. All radiation victims have the right to hold responsible individuals, corporations, and governments fully liable for negligent actions to the full extent of injuries inflicted.

Radiation Victims Roundtable

FIRST GLOBAL RADIATION VICTIMS CONFERENCE

236 Massachusetts Avenue, N.E. • Suite 506 • Washington, D.C. 20002 USA
Phone (202) 543-1070

ENDORSERS OF THE FIRST GLOBAL RADIATION VICTIMS CONFERENCE

ORGANIZATIONS

NORTH AMERICA

American Indian Environmental Council, Inc.
American Indian Movement
Atomic Photographers' Guild, Canada
Canadian Nuclear Veterans Association, Canada
Citizen Soldier
Citizens Call
Clergy and Laity Concerned
Colorado Atomic Agent Orange Veterans Coalition
Comite de Defensa Ecologico de Mexico, Mexico
Committee on Health Aspects and Management of Nuclear Power
Concerned Citizens of Manitoba, Canada
Environmental Coalition on Nuclear Power
Environmental Policy Institute
GE Stockholders' Alliance Against Nuclear Power
Greenpeace
Health & Energy Institute
Hiroshima/Nagasaki Peace Committee
Indian Health and Radiation Project
Institute for Security and Cooperation in Outer Space
Institute of Concern for Public Health, Canada
Interfaith Center on Corporate Responsibility
International Alliance of Atomic Veterans
Intercommunity Center for Justice & Peace
Jobs With Peace Campaign
LAND, Inc.
Lawyers Committee on Nuclear Policy
National Association of Radiation Survivors
National Coalition to Stop Food Irradiation
National Committee for Radiation Victims
National Mobilization for Survival
Nevada Desert Experience
New York West Side SANE
Nuclear Information & Resource Service
Nuclear Reform Project
Nuclear Weapons Freeze Campaign
Nurses' Alliance for the Prevention of Nuclear War
Peace Works
Peace, Inc.
People for Responsible Management of Radioactive Waste
Performing Artists for Nuclear Disarmament
Physicians for Social Responsibility/NYC
Prescott Peace Network
Public Citizen's Critical Mass Energy Project
Public Data Access
Radioactive Waste Campaign
Red River Peace Network
Resource Policy Institute
Riverside Church Disarmament Program
SANE
Southwest Research and Information Center
The Dodd Project for Radiation Studies
The Natural Rights Center
The Youth Council of Atlanta, Georgia
Three Mile Island Alert
Tonantzin Land Institute
U.S. Alliance of Atomic Veterans
U.S. Peace Council
United Methodist Board of Church & Society
Uranium Radiation Victims Commission
Women's International League for Peace and Freedom, U.S. Section
Workers' Policy Project
World Information Service on Energy (WISE), USA

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Amigos da Terra, Brazil
Amigos da Terra, Portugal
Asia-Pacific Peoples Environmental Network, Malaysia
Bertrand Russell Peace Foundation, England
Br25Paz, Denmark
British Nuclear Tests Veterans Association, U.K.
Campaign Against Dounreay Expansion, Scotland
Campaign for Nuclear Disarmament, England
Campaign for Nuclear Disarmament, New Zealand
Centro Regional de Estudio Nucleares de la UAZ, Mexico
Coalition for Peace and Development, Thailand
Consumers Union of Japan, Japan
Coordination Europeenne Des Amis de la Terre
Cumbrians Opposed to a Radioactive Environment, U.K.
Earthwatch, Ireland
Environmental Protection Society, Malaysia
EVY, (Energy Politica Association--Alternatives to Nuclear Power)
Federacion Canaria de "Los Verdes", Spain
Federation of Christian Churches, Pakistan
Forschungsinstitut fur Friedenspolitik, West Germany
Friends of the Earth (Sydney), Australia
Friends of the Earth Anti-Uranium Collective, Australia
Friends of the Earth International, The Netherlands
Friends of the Earth, United Kingdom
Fumicol Foundation Against Nuclear Testing, Sierra Leone
Gensuikin, Japan
German Peace Society-United War Resisters (DFG-VK), West Germany
Greenpeace, England
Hiroshima Interpreters for Peace, Japan
Institute for Energy & Environmental Research, W. Germany
Institute for Total Revolution, India
International Alliance of Atomic Veterans, Australia
International Associates for Community Health, Scotland
International Organizations of Consumers Unions, Malaysia
International Peace Bureau, Switzerland
Japan Council of Hiroshima Korean A-Bomb Survivors, Japan
Mallacoota Anti-Nuclear Group, Australia
Maralinga & Monte Bello Ex-Servicemens Association, Australia
Marshall Island Radiation Survivors, Majuro
Moitree Samaj Kalyan Sangha, Bangladesh
Movement Against Uranium Mining, Australia
National Committee for a Sane Nuclear Policy (COSNUP), India
Peoples Campaign Against Nuclear Energy, Sweden
Perak Anti Radioactive Action Committee, Malaysia
Polish Ecological Club - Krakow, Poland
Radiation and Health Information Service, England
Sahabat Alam Malaysia (Friends of the Earth), Malaysia
Scientists Against Nuclear Arms, Australia
Scientists Against Nuclear Arms, New Zealand
Scottish Campaign to Resist the Atomic Menace, Scotland
Shadows from Hiroshima, Switzerland
SOHYO, Japan
Sosjo Samidistrict, Samiland
The Green Party, West Germany
The Right Livelihood Awards Foundation, Sweden
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The Honorable Hilda Howland M. Mason, Council of the District of Columbia
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Anthony Mazzochi, Workers´ Policy Project
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Dennis Mosgofian, National Coalition to Stop Food Irradiation
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Jill Nelson, Jobs With Peace Campaign
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Kay Pickering, Three Mile Island Alert
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Tadashi Hizume.* Vamagata Prefecture Hibakusha Association, Japan
Kimi Honda, Doctor, Japan
John Hontelez, Friends of the Earth International, the Netherlands
Haruko Iijima,* Federation of Consumers, Tokyo, Japan
Juro Ikeyama, Nuclear Issue Specialist, Japan
Dr. Sadao Ichikawa, Gensuikin, Japan
Seiji Imabori,* Hiroshima Women´s College, Japan
Naruhiko, Ito, Professor, *Chuo University, Japan
Sakae Ito,* Hiroshima Prefectural Confederation of A-Bomb and H-Bomb Sufferers, Japan
Shigetoshi Iwamatsu, Professor, *Nagasaki University, Japan
Kazuyuki Iwasa, Radiation Victim from Suruga Nuclear Power Plant, Japan
Marina Jakobsen, Br25Paz, Denmark
Takayuki Kan, Drama Writer, Japan
Md. Rezaul Karim, Moitree Samaj Kalyan Sangha, Bangladesh
Darlene Keju-Johnson, Marshall Islander
Petra K. Kelly, MdB* The Green Party, West Germany
Johnson S. Khan, Federation of Christian Churches, Pakistan
Akira Kikuta,* Shizuoka Prefectural Trade Union Council, Japan
Sun-ei Kinjo,* Okinawa A-Bomb Survivors Council, Japan
Reishi Kondo,* Nagasaki Prefectural Trade Union Council, Japan
Dr. Bernd W. Kubbig, *Peace Research Institute, West Germany
Kei Kumai, Film Director, Japan
Matthias Kuntzel,* The Green Party, West Germany
Ohtori Kurino,* Peace Research Society, Japan
Takeshi Kurokawa,* General Council of Trade Unions of Japan, (Sohyo), Japan
Nobuo Kusano, Medical Scientist, Japan
Masahiro Ken Kuwahara, *Niigata University, Japan
Elaine Lawrence, Greenpeace, England
Zuah Soo Leck, Perak Anti Radiaoctive Action Committee, Malaysia
Shil Kun Lee,* Hiroshima Council of Korean A-Bomb Survivors, Japan
Monica Lind, Peoples Campaign Against Nuclear Energy, Sweden
Gauthier W. Loffler, Shadows from Hiroshima, Switzerland
Tetsuo Maeda, Military Issue Specialist, Japan
Ryo Maeno, Political Scientist, Japan
Ole-Sally Markussen, Denmark
Iri Maruki, Painter, Japan
Toshi Maruki, Painter, Japan
Yoshiko Matsui,* Citizens´ Group to Support Hibakusha in Korea, Japan
Nubuo Matsuoka,* People´s Research Institute on Energy and Environment, Japan
Frances McKie,* Campaign Against Dounreay Expansion, Scotland
Eric Miller, Movement Against Uranium Mining, Australia
Jan Minkiewicz,* Freedom & Peace, The Netherlands
V.C. Mohan, Asia-Pacific Peoples Environmental Network, Malaysia
Roger Moody, CIMRA, U.K.
Thys Moorlink, World Information Service on Energy (WISE), Australia
Mito Morihara,* A-Bomb Survivors Council of Japan Postal Workers Union, Japan
Churyo Morii,* Sohyo Local Industrial Unions´ Coordinating Council of A-Bomb Survivors, Japan
Ichiro Moritaki, Gensuikin, Japan
Yasuo Nakagawa,* Kobe University, Japan
Yoshio Nakatake,* Miyazaki Prefecture A-Bomb Survivors Association, Japan
Ryoshin Nakayoshi,* A-Bomb Survivors Council of All-Japan, Japan
Takeuti Naokazu, Consumers Union of Japan, Japan
Jean Nickels, Mallacoota Anti-Nuclear Group, Australia
Klarissa Nienhuys, The Netherlands
Masako Nomura, Japan
David J. Northey, Australia
Mary O´Donnell, Earthwatch, Ireland
Keiko Ogura, Hiroshima Interpreters for Peace, Japan
Buichi Oishi,* Anti-Nuclear Committee of One Thousand, Japan
P. Pierart,* University of Mons, Belgium
Dorothee Piermont,* The Green Party, West Germany
Jonathon Porritt, Friends of the Earth, U.K.
Mike Reid, British Nuclear Tests Veterans Association, U.K.
Magda Renner, Amigos da Terra, Brazil
Satoshi Roppongi,* A-Bomb Survivors Support Council of National Railway Workers´ Union, Japan
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Tokuhiro Shibatani, Biologist, Japan
Naruo Shiina,* Japan Tobacco Workers´ Union, Japan
Sumiko Shimizu,* Japan Women´s Congress, Japan
Takeshi Shinmura, Japan
Noriko Shintani, Singer, Japan
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Dr. Dhirendra Sharma, National Committee for a Sane Nuclear Policy, India
Gracelyn Smallwood, Aboriginal Australian
Dr. Henryk Sobanski, Polish Ecological Club - Krakow, Poland
Mikio Sumiya,* Tokyo Women´s University, Japan
Manami Suzuki, Japan
Jinshiro Takagi,* Citizens´ Nuclear Information Center, Japan
Yasuko Takemura, Japan
Olli Tammilehto, Energy Politica Association--Alternatives to Nuclear Power, Finland
Laddawan Tantivitayapitak, Coalition for Peace and Development, Thailand
Hew Soon Tat, Perak Anti Radioactive Action Committee, Malaysia
Ishiguro Toraki, Pastor, Japan
Ide Toshihiko, * Japan Federation of Nature Protection, Japan
Hiromitsu Toyosaki, Photojournalist, Japan
Atsushi Tsuchida, Japan
Saichiro Uesugi,* Buraku Liberation Union
Jakob von Uexkull, The Right Livelihood Awards Foundation, Sweden
E.C. Van Munster, International Alliance of Atomic Veterans, Australia
Undine von Blottnitz, MdEP, West Germany
Joe Wacher, Friends of the Earth, Australia
Reiko Watanuki, Japan
Tony Webb, Radiation and Health Information Service, England
Prof. Bob White, Scientists Against Nuclear Arms, New Zealand
Dr. Peter Wills, Scientists Against Nuclear Arms, New Zealand
Loh Sin Yam, Saharat Alam Malaysia (Friends of the Earth), Malaysia
Keizo Yamada, Professor, *Sofia University, Japan
Akira Yamagishi,* A-Bomb Survivors Council of Japan, Japan
Yukio Yamakawa, Japan
Shunzei Yamazaki, Japan
Tazuko Yasui, Japan
Shigeru Yoshimatsu, Pastor, Japan
Reiko Yukawa, Songwriter, Japan

NATIONAL COMMITTEE FOR RADIATION VICTIMS

TESTIMONY OF E. COOPER BROWN, ESQ. & KATHLEEN M. TUCKER, ESQ.

BEFORE

THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
&
THE SUBCOMMITTEE ON NUCLEAR REGULATION OF THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

JUNE 12, 1985

Good morning, Senators. My name is E. Cooper Brown, and I am the President of the National Committee for Radiation Victims and former general counsel for the National Association of Atomic Veterans. With me today is Kathleen M. Tucker, a member of the board of directors of the National Committee for Radiation Victims and president of the Health and Energy Institute, which is conducting Radiation Litigation Seminars and will soon produce a Radiation Law Reporter. We are both attorneys, and we appear today on behalf of the plaintiffs bar. We thank you for the opportunity to present our comments on the Radioepidemiological Tables which could have an impact on thousands of claims for radiation injury by those living near the Nevada Test Site, nuclear weapons facilities, or nuclear power plants, as well as on atomic veterans, nuclear workers, uranium miners, medical radiation workers, and others exposed to ionizing radiation.

The underlying concern we all share in regard to the Radioepidemiological Tables is the issue of justice. We certainly do not contend that all cancers are caused by radiation, and the concept of summarizing scientific knowledge on the relationship of radiation and various cancers appeared to be a favorable idea. We were hopeful that the tables mandated by the 1983 Orphan Drug Act would provide a useful guide to evaluating the probability of radiation causation that would aid both radiation victims and their attorneys in

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evaluating potential claims for injury. Unfortunately, the procedures used to establish the "Ad Hoc Committee to Develop Radioepidemiological Tables" resulted in establishing a biased panel which we believe has developed Tables which underestimate radiation risks.

Justice is often an illusive goal. We understand that these committees share our goal to achieve justice, and we hope that these hearings will serve as the basis for further steps that could move us closer to the goal of true justice for radiation victims. Many radiation victims are currently seeking compensation in state and federal courts through the tort system. Under the tort system, both plaintiffs who claim injury and defendants charged with responsibility for injury are given opportunities to present evidence and witnesses to the fact finders. It is our understanding that the idea behind the tables was to simplify the often laborious and expensive process of bringing forth witnesses and evidence in radiation cases by providing a summary of the scientific research in the form of radiation risk tables. We do not feel that the present tables embody the goal. Instead, the tables reflect the opinons of expert witnesses for defendants in radiation litigation, advocates for the nuclear industry, and scientists who might at least be regarded as neutral on the issue. Plaintiffs expert witnesses and scientists who have challenged current federal radiation exposure standards publically were excluded both from the panel and from the review process. Use of the Tables to determine the right to compensation would be tantamount to holding a trial on a radiation claim and only allowing the defendants to offer testimony. We do not think that the interests of justice would be served by using the present tables for anything more than a guide to the literature on radiation health effects.

The U.S. federal government cannot claim an admirable record on warning its citizens about the hazards of ionizing radiation. Instead, the federal government urged citizens to go out and watch atomic detonations, rather than urging them to take shelter from fall out. In the decision of Allen v. U.S.A. Federal Judge Bruce S. Jenkins states:

> Considered as an evolving whole, the public education program in off-site communities was consistently heavy with confident reassurances. Important information concerning both risks and effective precautions was scarce at best, and largely ineffective as a rule...
>
> At the most fundamental level, the Government's failure to educate, to inform and to warn deprived those people living in the off-site communities of Utah, Nevada and Arizona of an opportunity -- the opportunity to protect themselves, at least as far as was practical; the opportunity to evaluate the question of risk for themselves and their children; the opportunity to choose to leave the area of increased risk, or to choose voluntarily to stay. Allen v. U.S.A., U. S. District Court, District of Utah, Central Division, No. C 79-0515-J at 313-315 (May 10, 1984).

Federal activities went even further to reassure citizens about atomic fallout. In the spring of 1953 thousands of sheep were lost downwind of the Nevada Test Site following atmospheric atomic tests. Congressional hearings held in 1979 revealed that the federal government engaged in a concerted effort to disregard and to discount all evidence of a causal relationship between exposure of the sheep to radioactive fallout and their deaths. Judge A. Sherman Christensen, who had originally denied compensation to the sheep ranchers in federal court, ruled that a fraud had been perpetrated on his court and reopened the case in August of 1982. That case is now on appeal. Two of the researchers involved in the sheep case fraud upon the court were later placed in charge of studies into the radiation health effects on nuclear workers at Department of Energy facilities.

When scientists warned that atmospheric fallout would lead to thousands of deaths, the Atomic Energy Commission asked Dr. John Gofman and Dr. Arthur Tamplin to study radiation health effects at Lawrence Livermore Laboratory. When the researchers warned that if the average exposure of the U.S. population were to reach the allowable 0.17 rads per year there would in time be an excess of 32,000 cases of fatal cancer plus leukemia per year--year after year--and urged a tenfold reduction in allowable radiation exposure, they were drummed out of government employment. They found their papers censored, their budgets cut, their staff removed, until they finally left the Atomic Energy Commission employment. These researchers were clearly being punished for warning of radiation dangers and challenging federal radiation policy.

Dr. Thomas Mancuso, an industrial hazards epidemiologist, also found his funds cut when he refused to downplay radiation hazards. Atomic Energy Commission officials demanded that Dr. Mancuso sign a press release denying a cancer increase uncovered at the Hanford site by a Washington state public health physician, Dr. Samuel Milham. When Dr. Mancuso refused, his contract officer, Dr. Sidney Marks, initiated the paperwork to prevent authorization of future research funds. Dr. Marks then left the Atomic Energy Commission to take over the Mancuso study. Dr. Marks was involved in the fraud upon the court in the Utah sheep case.

Later Congressional hearings revealed that Dr. Mancuso had received favorable peer reviews, suggesting that his work be expanded, except for Dr. Sidney Marks. Before all funds could be terminated, Dr. Mancuso enlisted the aid of reknowned epidemiologist Dr. Alice Stewart and her statistician George Kneale. They published a paper indicating increased risks of bone marrow cancer (multilple myeloma), pancreatic cancer, and lung cancer for workers who received allowable doses under federal standards. The Atomic Energy Commission successor agencies tried to confiscate Dr. Mancuso's data base, and then circulated substantially less complete data to other researchers seeking to refute the Mancuso findings.

Dr. Irwin Bross of Roswell Memorial Institute was studying potential radiation damage from medical procedures in the Tri-State Survey. He criticized the use of mammographies, warning that their high exposures would cause more cancers than they cured. A peer review committee of radiologists urged an end to his funding, even though they lacked credentials as epidemiologists. Dr. Bross' challenge to federal radiation standards resulted in an end to his federal funding.

Because of these examples, it would not be surprising if federally funded researchers felt that challenges to federal radiation standards might result in economic reprisals. Against this history of federal suppression of radiation dangers, it is important that radiation risk tables be prepared by scientists of the highest integrity if they are to achieve public acceptance and avoid court challenges.

The panel chosen to serve as the "Ad Hoc Committee to Develop Radioepidemiological Tables" was challenged by radiation victims organizations soon after they learned the panel composition. The panel contained three scientists who testified against radiation victims on behalf of the federal government, Dr. Seymour Jablon, Dr. Arthur Upton, and Dr. Charles E. Land. The panel contained none of the experts who testified on behalf of plaintiffs in the Allen v. U.S.A. case or other lawsuits. It appeared that the federal government hoped to limit liability for past radiation actions by downplaying current radiation health effects.

This fear was confirmed when Dr. Seymour Jablon coordinated a study of atomic veterans who were early entrants to Hiroshima and Nagasaki after the atomic bombings in 1945. Science magazine reported that the study "was intended from the outset to serve a primarily political, not scientific, purpose." (SCIENCE, v. 221, no. 4612, p. 733, Aug. 19, 1983). The National Association of Atomic Veterans challenged the study and persuaded members of Congress to ask for a review by the Office of Technology Assessment (OTA) because the researchers had not even contacted all of the multiple myeloma victims already identified through the work of the Hiroshima/Nagasaki Veterans. Although the Jablon study concluded that no unusual levels of bone marrow cancer were found among former U.S. servicemen who entered the atomic-bombed cities of Hiroshima and Nagasaki after World War II, the OTA Review found that the study did not support the conclusion.

> Except for assuming a population at risk of 20,000, at each step of the way the Council's methods contribute to an underestimation of the observed and an overestimation of the expected numbers of cases, making it less and less likely that an excess would be detected, even if it did exist." *

A reasonable person might easily conclude that the Jablon study was lying and cheating. A reasonable person might conclude that they could not trust Jablon to provide honest answers about radiation health damage to atomic soldiers or others. If political motivations might sway one study, couldn't it sway others?

Dr. Rosalyn Yallow was appointed to replace a panel member suffering from poor health. Dr. Yallow has made such biased and inaccurate statements as "There is absolutely no evidence that low levels of radiation are harmful to human health," and "Low level radiation is safe," despite universal agreement among reputable scientists that there is no "safe" level of ionizing radiation. Dr. Yallow went so far as to suggest that Utah citizens "are the healthiest in the nation, and if anything, it seems as if the radiation is good for you."

Scientists who have denied radiation dangers or sanctioned improper studies to hide radiation effects have no place on panels developing radiation risk tables. Yet these scientists were chosen and scientists who warn of

*OTA Staff Memorandum, Review of the Report on Multiple Myeloma Among Hiroshima/Nagasaki Veterans, p. 22 (Dec. 17, 1983).

higher than predicted cancer rates from current federal standards were excluded, as were scientists who have testified on behalf of radiation victims.

The composition of the National Academy of Scientists oversight panel does not overcome the problems of the Rall panel. Once again, three members of the panel have testified on behalf of the government or the defendant in radiation claims, while none of the experts testifying on behalf of radiation victims were included. Dr. Saenger, Fabrikant, and Webster have all testified for the defense, but the presence of Dr. Saenger on the panel is bound to undermine public confidence.

In 1978 Congressional Hearings Congressman Doug Walgren stated:

> Dr. Saenger's experiments read like something out of Frankenstein. There is no getting around that. The relationship between Dr. Saenger and the Department of Defense seems quite clear, at least to great parts of the public who have to rely on the results of your study.*

Congressman Walgren was referring to Department of Defense financed studies conducted by Dr. Eugene Saenger at the University of Cincinnatti in which cancer patients were exposed to total body irradiation to gather data on how soldiers might fare on the nuclear battlefield. The subjects were 87 cancer victims who were poor (84 out of 87 were charity patients), mostly black (61 out of 87), with little education (mean education 5 years). Most of the patients were clinically stable, and many of them were working daily, but after whole body irradiation treatment of up to 250 rads, 25 out of 87 patients died within 60 days. Through the years of this experiment using doses up to the 250 rad range (when doses between 250 and 300 were expected to be lethal for half the people so exposed), there was no indication of therapeutic value in reports filed with the Pentagon.

*Effect of Radiation on Human Health, Hearings before the Subcomm. on Health & the Environment of the Comm. on Interstate and Foreign Commerce of the House of Representatives, 95th Cong., 2nd Sess. p. 809 (Jan. 24-Feb. 28, 1978).

Although patients were told that their radiation exposures would help their sickness, The Junior Faculty Association of the University of Cincinnati condemned these experiments, saying:

> ...we have come to the conclusion that many patients in this project paid severely for their participation, and often not knowing that they were part of the experiment. We feel that the evidence clearly calls into question the manner in which these human experiments were designed and carried out. (Junior Faculty Association report cited in Drug Research Reports, v. 15, no. 7 at S-21, Feb. 16, 1972).

Diagnosis of cancer does not strip a citizen of his or her right to the best available medical care, yet Saenger apparently felt justified in pursuing these experiments because the patients were eventually going to die of their diseases and the federal government wanted the information being provided. Death was apparently hastened by the radiation exposures, and seven subjects died within 20 days of the radiation exposure, when bone marrow damage from radiation peaks.

Civilized societies label such human experimentation barbarous, since the treatments were not intended to aid the victims and many were not even informed of the experiments. Would a reasonable person trust the advice of someone who engages in such experimental research? We think not.

It is not surprising that tables developed by scientists whose views range from neutral to defensive of radiation mitigate projected radiation risks. We have requested that some of our scientific advisors review the Tables, and we have forwarded copies of the Tables at our own expense when we learned that the Tables had not been forwarded by the Committee or the panel. We await their detailed comments, but we want to make the following points about the tables:

1. The Tables rely primarily on data from studies of groups exposed to high doses of radiation over a short period of time. More recent studies of people exposed to low doses of radiation over long periods of time have been ignored or discounted without adequate explanation. It is quite possible

that different biological mechanisms are at work. For example, high dose exposures in a short time period may cause greater damage to the bone marrow, resulting in leukemias as found in A-bomb survivors. Lower doses may be more likely to cause solid tumors as found in Hanford workers. Excluding the authors of studies evaluating people exposed to low doses could have been compensated for by including their findings in the formulations, but some recent studies are not even cited in the footnotes.

2. The A-bomb survivor studies are one of the main sources of data used by the panel. Although panel members admit that dose reevaluation for A-bomb survivors will lead to significant increases in risk estimates (They cited increases ranging from 50% increases to 250% as possible), the panel wants the current underestimations of risk embodied in the tables to become the standard risk estimates for the next five years.

3. The formulas developed would have the effect of denying compensation if applied to some of the cases already decided in favor of radiation claimants. For example, if these tables were applied in the Allen decision, at a 10% probability level only six out 24 plaintiffs would prevail, instead of the ten granted compensation. At a 50% probability level, two might have prevailed, giving the most favorable construction, The fact finder in the Allen decision heard arguments from both sides. If the Tables became a legislative remedy, there would be no opportunity for the plaintiff to prove his or her claim.

The Tables could be used in other arenas, like the Veterans Administration. Out of eight leukemia cases awarded compensation by the Board of Veterans Appeals, the 10% probabilty level would have allowed compensation for half of the eight awards, and at the 50% probability level none would have won.

4. BEIR III states that seven other cancers can be expected for each radiation induced leukemia, while the Tables suggest only three cancers for each leukemia. This trend to reduce the number of expected cancers is not justified within the report and further raises public concern over the objectivity of the report

5. Dr. Rosalie Bertell pointed out that the tables use a mathematical formula which requires that a doubling dose for a cancer be attained before the probability of causation can be more than 50%. In other words, a dose expected to double the risk of cancer would have to be reached before the common "preponderance of the evidence" standard could be shown by a claimant. This clearly places a far greater burden on plaintiffs than is warranted.

6. The proposed updating of the tables every five years would prevent claimants from benefitting from new research as it is produced. Studies which might show increases in lung cancer among folks living near a nuclear test site, appearing the year after a review, would not be considered for another four years. Claimants may have cases decided before the panel could incorporate the information. (This assumes that a newly constituted panel will consider low dose studies, as a responsible panel would.)

Although radiation victims organizations were told they could have their say at spring hearings when they requested an opportunity to testify at hearings of this Committee last fall, we were specifically warned not to bring any radiation victims to the table at this hearing. We know that several victims organizations wanted to testify, and still do want to testify. The nuclear industry and the federal government, defendants in radiation litigation, have been provided an ample opportunity and more time than we to present their views. We strongly protest the exclusion of radiation victims from this process as undemocratic and unjust.

RECOMMENDATIONS

In light of the concerns that have been raised by the various witnesses to these proceedings before this Committee, we would recommend several actions that should be undertaken at this time:

1. The Office of Technology Assessment should be asked to investigate the process by which Ad Hoc Committee members were selected and to advise this Senate Committee about the issues and concerns that have been raised about the present Tables.

2. The tables and methodology developed by the Ad Hoc Working Group for Health and Human Services should be submitted to public comment by publication in the Federal Register for review pursuant to the requirements of the Administrative Procedures Act. (See attached memo on APA, which discusses how these Tables constitute "legislative rules" subject to the APA.)

3. An additional half-day of hearings should be held before this Senate Committee to begin redressing the favoritism shown to radiation defendants by allowing radiation victims and independent scientists an equal opportunity to be heard and to assist this committee with their expertise and concerns.

4. A more balanced panel should be appointed after deficiencies in the process have been identified and after consultation with all interested and concerned parties. In the meantime, the Tables should be placed "on the shelf," with it being made explicitly clear by this Committee that the tables and the report are not to be used before any tribunal adjudicating radiation cancer claims.

We have appended curriculum vitae for Dr. Alice Stewart, Dr. Rosalie Bertell, and Dr. Karl Morgan, along with a brief summary of Dr. John Gofman's accomplishments. We think their qualifications merit far more scientific credibility than some of the panel members or NAS oversight members. We demand equal access to the process of decision making for both sides of this controversy. Those truly interested in justice for radiation victims will support this demand for fairness. Those interested in promoting the interests of the radiation industries or in limiting the liability of the federal government for radiation damage will not support us. Senator Hatch, we hope that you will choose to side with your own constituents and get this process opened up so that justice has an opportunity to prevail.

NATIONAL COMMITTEE FOR RADIATION VICTIMS

Senator Simpson's Questions for the record
for E. Cooper Brown & Kathleen M. Tucker

1. As I understand your position, you object to the "probability of causation" tables because the panel that assembled the tables was unfairly biased in the direction of the viewpoint that radiation risks are less significant than you, or the organizations which you represent, have concluded. If the group that prepared these tables were to have included representatives from the "independent scientific community" that you have suggested, would you then support the "probability of causation" approach as a means of compensating radiogenic cancer claimants?

The probability of causation approach to compensating radiogenic cancers could be a useful tool to help evaluate whether a cancer was likely to have been caused by radiation exposure, but probability of causation methodology must take into account a variety of factors. The current radioepidemiological tables are based on extrapolation from high dose exposures to low dose exposures, fail to make adjustments for changes in dose estimates on Hiroshima-Nagasaki survivors, (despite panel assumptions that those revisions will increase risk estimates) and fail to take into account recent epidemiological research that suggests greater risks to humans at lower dose exposures extended over a long period of time. All of these problems result in tables that tend to underestimate radiation risk.

Any set of tables will have inherent limitations--such as the inability to incorporate new data as it appears in the literature. Under the proposed use of the Radioepidemiological tables, a person suffering prostrate cancer after exposure to tritium would be denied use of a recent study which found increased prostrate cancer in a British nuclear workforce (Beral, et. al., "Mortality of workers of the United Kingdom Atomic Energy Authority 1946-1979," 219 British Medical Journal p.440 [Aug. 17, 1985.]) He and others similarly situated would be expected to wait five years before the panel considered this new evidence and could determine how to incorporate it into the tables. Since a decision on compensating that individual must be reached through normal channels, the tables concept can result in compensation lagging far behind scientific knowledge. This is one of the reasons we oppose basing all compensation decisions exclusively on any probability of causation tables.

2. The Veterans Administration is currently considering whether it should employ the probability of causation methodology in the regulation that it is now developing under the "Veterans Dioxin and Radiation Exposure Compensation Standards Act." Do you support the use of this methodology by the Veterans Administration in that context?

We do not support the use of the Radioepidemiological Tables in the context of the "Veterans Dioxin and Radiation Exposure Compensation Standards Act."

3. Have you undertaken an analysis of the "probability of causation" approach, and compared the results that you would reach if this approach were applied by the courts in any of the cases that you have been involved in, rather than the traditional tort approach presumably applied by the courts?

We applied the Radioepidemiological Tables to the Allen decision, and our calculations indicated that fewer plaintiffs would have been granted compensation using the Tables. We found that at best, and using a 10% probability of causation, only 6 plaintiffs would have recovered out of the 10 who did recover damages in Allen. In applying these Tables to those granted benefits by the V.A., only 4 of the 8 leukemia cases awarded benefits would have recovered if the tables were used using the low 10% value. Statistician Dr. Rosalie Bertell has analyzed the use of the Radioepidemiological Tables in regard to erring in favor of either not compensating true radiation victims or compensating non-victims. In the attached memorandum dated July 2, 1985, she states "I can only conclude that the Working Group has achieved an extreme methodology (assuming the 50% rule) for eliminating almost all False Positives (compensated non-victims) at the cost of maximizing the number of False Negatives (uncompensated victims)." We conclude that under the Radioepidemiological Tables, many legitimate radiation victims would be denied compensation, while under our current tort approach, these victims would have an opportunity to present the best available evidence to support their claims. While decisions may vary between judges, at least not all errors would be expected to deny compensation.

4. If one is to accept the premise that, based on our current scientific knowledge, it is next to impossible to prove that a given cancer was or was not caused by an earlier dose of radiation, how do you respond to the claim that, under our current tort approach to these cases, a claimant will either be overcompensated or undercompensated, depending upon where the judge decides to impose the burden of proof?

In your letter to me of May 17, 1985, you raise a number of questions about the assumptions and data that went into developing the probability of causation tables, arguing that those assumptions underestimate the risk of radiation. Along that line, I have three questions:

A. Based on your most recent data, how many cancers occur in the United States annually, from all causes?

According to World Health Statistics 1984 (pages 178, 180, 182), all types of cancer accounted for 416,509 deaths in the United States in 1980.

B. Of this total number, how many are related to radiation exposure?

C. Of those related to radiation exposure, how many are the result of natural background exposure? How many are related to weapons testing and fallout?

The whole argument over radiation health effects would be over if there were a generally accepted answer to the question, "How many cancers are related to radiation exposure?" Most scientists will agree that some cancers are more probably caused by radiation exposure than others, although radiation is apparently capable of producing cancer in any human tissue.

We could choose a larger percentage than the panel chose, supporting our claim with studies ignored or discounted by the panel, and give you a number as an answer. We could use the same method and give you numbers from a high to a low proportion. We are reluctant to do so because there is very little data evaluating natural radiation exposure and its relationship to cancer. Current environmental radiation measures now include exposures related to weapons testing and fallout, making it difficult to separate the two sources of exposure.

The legislature wants answers that can be relied upon, but one can not work backwards from an assumption and get an answer. The panel blithely claims that "less the 3% of the U.S. cancer burden can be plausibly attributed to ionizing radiation." We challenge this unwarranted assumption, and caution legislators to do the same. From the 3% assumption, one can provide a number that might look reliable, but that number could easily be wrong.

Senator Hatch's Questions for the Record:

Our second panel consists of two representatives of the National Committee for Radiation Victims, Mr. Cooper Brown and Ms. Kathleen Tucker. We are pleased to have you here.

1. Mr. Brown, you seem to have been the focal point of many of the allegations that these hearings are somehow biased, but I note that you are here, and immediately following the Justice Department. I don't know where people got the notion that a Congressional hearing should be or could be an ultimate forum for deciding the credibility, validity and degree of certainty of the radioepidemiological tables or the value of the NIH report. We only begin the process here. I expect the debate to continue in both scientific and legal journals, and in scientific symposia and in the courts. It could not be otherwise. In light of this fact, and in light of the fact that you are, after all, here, don't you think you over played your hand a bit?

The exclusion of independent scientists who have testified on behalf of radiation victims from the panel which developed the radioepidemiological tables, followed by intentional exclusion of radiation victims from testimony before these Senate hearings when radiation defendants were amply represented, suggested that the process being initiated was extremely one-sided. While the debate over the tables can be expected to continue, we feel radiation victims have just as much right as the radiation defendants to participate in the process. We appreciate the Senate opportunity to present some of the victims' concerns, but reiterate that safeguards for victims rights must be instituted regarding any radiation risk tables, especially publication in the Federal Register to allow comment by scientists and citizens.

2. What do you think of the "discretionary exception?" Do you think that the federal government should be liable for negligent acts that harm American citizens?

The "discretionary exception" may have legitimate purposes and functions, but it should not be extended to shield the federal government from liability when its agents condemned unnamed citizens to death from latent cancers. It is no more morally acceptable or justifiable to shoot people with invisible bullets of radiation than it is to shoot them with lead bullets. The record clearly demonstrates that in the interests of national security our federal government chose to sacrifice the lives of citizens exposed to atomic fall-out in order to develop and test nuclear weapons. The negligent acts of government agents and federal nuclear promotion policies combined to end the lives of some of our citizens prematurely, and the government should accept responsibility for those acts by providing compensation to the victims and their families.

3. Do you think that "probabilistic" evidence should be admissible in court? In principle, do you think that probability tables would be useful?

Probability tables could be useful if they are based on the most appropriate scientific research and if the limitations of such tables are clearly identified. Probabilistic evidence is already admissible in court, and good fact finders will give the evidence appropriate weight. Probability Tables should not be substituted for individual evaluations of claims, nor should the development of a formula be substituted for the needed epidemiological research.

4. Do you think that the law suffers when its application is so irregular as to seem capricious? Do you think that something should be done to straighten the mess out?

Of course the law suffers when its application is so irregular as to seem capricious. If the Senator is suggesting that differing outcomes in recent cases involving radiation litigation has been irregular, we would probably be in agreement. While it would be helpful to get greater regularity in judicial decisions, we feat that the Radioepidemiological Tables will be used to uniformly deny compensation to radiation victims. This would sacrifice justice for regularity in outcomes, something we all hope to avoid. Since the appellate process is in part designed to reconcile differing legal opinions, it might be wise for Congress to move slowly in intervening before the appellate courts have reviewed some of the present lower court decisions.

5. You have seen the difficulty we had yesterday in approaching an adequate discussion of the science involved with the tables. Do you think that courtrooms are a proper place for scientific debates involving protracted discussions of scientific minutiae. Don´t you think that there is a danger that emotionality and drama might be overly persuasive when the courtroom is used as a forum for scientific deliberation? Much of the Allen decision is an uneven facsimile of a physics text book. Do you think that judges should have to become 90 day Ph.D´s to write a legal opinion? Don´t you think that this delving into the science by attorneys and judges gets a bit presumptuous and specious?

The courtroom utilizes a process where the plaintiff and the defendant are both allowed to offer evidence to support their claims. Despite its faults, we believe the American judicial system is designed to seek both truth and justice. We do not think that scientific debate should be confined to those scientists employed by the government to develop a documents which can be used by the government for its own defense in court. The fact finder, whether judge or jury, should be given the opportunity to evaluate the evidence of both plaintiffs and defendants. If the Radioepidemiological Tables were substituted for the courtroom process, it would be like substituting testimony from defendants' experts for the current pro and con debate. Clearly, this is not the American way.

We do not regard science as the exclusive province of government paid scientists, and our society would be making a grave mistake if it tried to elevate scientists to a god-like status. Judges and attorneys are trained to engage in rational debate and rational evaluation. They are expected to learn some basic medical terminology when handling medical malpractice cases; consequently, learning basic physics terminology for radiation cases is not anything unusual. Certainly, some judges and juries will prove better at learning these basics than others. If a judicial opinion reflects a good comprehension of the underlying terminology, we can place greater confidence in that decision.

Unless we choose to adopt a national policy which allows defendants immunity if their crime involves complicated or latent damage, we must expect our tribunals to address the many complicated issues confronting modern society. Certainly it is simpler to decide a physical battery case involving an obviously bruised victim with witnesses to identify the assailant who used a baseball bat. Cases of battery in which the immediate damage is not visible to the eye, and which can only be diagnosed at a later date (such as cancers with long latency periods), are obviously more difficult to address. However, it is just as important to prevent chemical or radiation batteries that cause invisible damage that does not become manifest for years.

6. Yesterday, Mr. Alvarez mentioned Galileo, and suggested that he had reappeared in the person of Dr. Alice Stewart. But there is also Lamarck who believed in evolution through acquired traits. Maybe she is he. The point is that Galileo was ultimately proved right and Lamarck was proved wrong. One fate or the other awaits Dr. Stewart. If she is right, public policy will ultimately catch up with her. In the meantime, since there will never has been nor will be complete agreement among putative experts, the courts must go with the preponderance of scientific opinion. The

outliers will just have to fight it out with the middle until the former fail or prevail, but the arena for this scientific contest must be a scientific forum, and not our courts of law. Do either of you really think that court rulings should reflect other than mainstream scientific opinion?

One of the key issues in the radiation controversy is whether low dose radiation exposures over a long period of time result in the same damage as a high dose exposure in a short period of time. Most of the epidemiological data currently being used to estimate radiation risks comes from studies of high dose exposures in a short time period, namely the A-bomb survivor studies and studies of patients exposed to high doses of x-rays. The work of Dr. Alice Stewart et. al. in studying workers occupationally exposed to low doses of radiation over years suggests that there may be greater radiation risks at lower doses over longer time periods than current exposure standards assume. Studies of other worker populations are underway, and some have already supported the Stewart viewpoint.

We think that court rulings should reflect an honest effort to determine the truth. When an issue is controversial, it is often difficult to determine what is the "mainstream" scientific opinion. For years, the tobacco industry argued that cigarette smoking was not very hazardous. They offered scientific studies to support their claims. The radiation industry makes the same argument now for radiation exposures. The majority of federally funded radiation health effects research is sponsored by the Department of Energy, a prime defendant in radiation damage claims. Some may argue convincingly that these studies are akin to the studies proffered by the tobacco industry.

Reputable scientists agree that there is no level of ionizing radiation so low that it cannot cause harm to living tissue. There is no "safe" level of ionizing radiation. There is no other "mainstream" scientific opinion on radiation health effects, but rather a debate. Only adequate, independent epidemiological research can answer our questions and settle the debate. Congress should transfer research funds from the Department of Energy to a public health oriented agency so that the public can place greater confidence in the results of our research tax dollars.

Coalition for Alternatives in Nutrition and Healthcare
(C A N A H)
P.O. Box B-12
Richlandtown, PA 18955

CAUSES OF DEATH

1980

UNITED STATES OF AMERICA

Compiled by World Health STATISTICS 1984 pages 178, 180, 182

Causes of Death:

#1 - Circulatory diseases (all catagories)	993,348
• acute myocardial infarction 299,584	
• other ischaemic heart diseases 266,171	
#2 - Cancer (all types)	416,509
#3 - Respiratory diseases (all catagories)	125,092
• pneumonia 51,917	
• bronchitis, emphysema, asthma 20,496	
• other respiratroy diseases 52,679	
#4 - Accidents and adverse effects	105,718
#5 - Diabetes	34,851
#6 - Liver disease	30,583

HEALTH & ENERGY INSTITUTE
236 Massachusetts Avenue, N.E. • Suite 506 • Washington, D.C. 20002 U.S.A. • Phone (202) 543-1070

December 4, 1984

TO: Those concerned about compensation for radiation injuries from any source.

FROM: Kitty Tucker Kitty

RE: Proposed epidemiological risk tables for radiation injuries

Congressional activity is underway that could have an adverse impact on all those who seek compensation for radiation injuries or illnesses. Your immediate assistance in this matter is urgently needed.

Senator Orrin Hatch of Utah has requested the preparation of radioepidemiological tables for a possible legislative compensation scheme for citizens downwind of the U.S. atmospheric atomic tests conducted during the 1950's and early 1960's, and HHS set up an "Ad Hoc Working Group to Develop Radioepidemiological Tables." (See enclosure for listing of members.) The composition of this appointed group suggests that any resulting report will seriously underestimate health hazards due to ionizing radiation. In fact, Dr. Karl Morgan, a founder of the health physics profession, has suggested that the Group would be most appropriately called "The Hatchet Group."

The group is composed of well known scientists, and their pronouncements could set the standards for all classes of compensation for delayed radiation injury, including workers' compensation. Only immediate action can prevent the potentially biased report of this group from becoming a standard that seriously underestimates actual long term health damage from ionizing radiation.

Several of the group members who have been funded by the federal government for years are not expected to arrive at the most honest answers possible regarding radiation hazards. Some are protecting their conclusions from studying atomic bomb survivors exposed to high doses of radiation over a short time period, and they appear to be unwilling to admit that dangers from low exposures over a longer time period may have seriously different health impacts. In the recent scientific debate over the health hazards of low level radiation, several epidemiological studies have demonstrated increased risks of cancer among workers or others exposed to supposedly "safe" levels of ionizing radiation. Not one of the scientists warning of the greater than predicted health impacts have been included in the "Group."

On the other hand, some of the Group members have demonstrated their willingness to assist the federal government in downplaying radiation dangers to avoid the federal government being forced to compensate large numbers of people injured by federal radiation activities, including atomic veterans, those downwind from nuclear test sites, and federal nuclear workers.

For example, Group member Dr. Seymour Jablon oversaw a study of the incidence of multiple myeloma (bone cancer) among soldiers who were early entrants to Hiroshima or Nagasaki after the atomic bombings in 1945. These soldiers were exposed to residual radioactivity in the air and water and food. The atomic veterans had identified 28 cases before a study was initiated under Jablon. By ignoring some of the identified cases and using an inappropriate study design, Jablon's group reported no increased risk of multiple myeloma. A subsequent report of the Office of Technology Assessment, requested by Congressmen Paul Simon, Thomas Daschle, Lane Evans, Bob Edgar, Kent Hance, Timothy Penny and J. Roy Rowland, detailed the faults of the Jablon report and concluded that the results were invalid. The OTA report stated:

> "Except for assuming a population at risk of 20,000, at each step of the way the Council's methods contribute to an underestimation of the observed and an overestimation of the expected numbers of cases, making it less and less likely that an excess would be detected, even if it did exist."

Dr. Rosalyn Ya'ow is well known for her defense of the nuclear industry and her willingness to downplay radiation dangers. She is quoted as stating, "There is absolutely no evidence that low levels of radiation are harmful to human health." Despite the fact that the scientific community agrees that there is no "safe" dose of radiation, she has stated, "Low level radiation is safe."

Three members of the Group testified on behalf of the federal government against citizens who were exposed to atomic fallout from the Nevada test site during the atmospheric atomic testing program, but none of the scientists who testified on behalf of the radiation victims were invited to serve on the panel. Yet, when a federal judge had the opportunity to hear evidence from both sets of scientists, he ruled in favor of several of the cancer victim plaintiffs, accepting the testimony of their scientists, and granting a multimillion dollar judgment in a carefully worded decision in the case of Allen v. U.S.A.

Participants in the Radiation Victims Roundtable, a semiannual gathering of representatives of radiation survivor constituent groups (who represent atomic veterans, downwinders, workers, and those living near nuclear production facilities) and supporting service groups, have asked for a lobbying campaign to prevent the results of the Ad Hoc Group from becoming an obstacle to securing compensation for radiation injury. The campaign will be two pronged:

1. It will challenge the objectivity of the current group and seek a more objective body to draft tables and an even more objective review body.

2. It will seek establishment of an alternative Commission composed of prominent independent scientists who are free from conflicts that would impair their ability to objectively assess the dangers of radiation injury.

To accomplish the first goal, it is important to inform the Congress and the public of the potential bias of the "Group" as currently constituted. We hope that you will consider publishing an article in your membership newsletter and that your staff will bring this matter to the attention of appropriate elected officials. Letters to Senator Hatch should be sent to the Senate Committee on Labor and Human Resources, 428 Senate Dirksen Office Building, Washington, D.C. 20510, with copies to Senator Kennedy, ranking Democrat on the Committee.

The second goal of establishing an alternative Commission to evaluate risks was suggested by Dr. Rosalie Bertell, who has initiated an excellent publication, the HANDBOOK FOR ESTIMATING HEALTH EFFECTS FROM EXPOSURE TO IONIZING RADIATION. Dr. Bertell would like to establish a scientific meeting to review and revise the data collected in the HANDBOOK through open scientific debate. If our tax dollars can be used to fund scientists who downplay radiation hazards, they should also be used to fund scientists who recognize such hazards, so that the broader community can evaluate the arguments of both sets of scientists in this ongoing debate over the full range of risks of damage from ionizing radation, including the potential damage to our offspring.

The Health and Energy Institute will be following this issue closely, and collecting information from various groups regarding this issue. Please contact the Institute if you have any questions about this issue, or if you can provide assistance in this matter. We would also appreciate copies of correspondence with Congress and others regarding this issue crucial to justice for radiation victims.

Radiation Victims Bill of Rights

Preamble

WHEREAS millions of people have been and are currently exposed to ionizing radiation—on the job, in military service, as medical patients and as medical personnel, in communities near or downwind from testing sites, uranium mines, mills, or tailings piles, in the area of reactors, weapons plants, waste sites, and other nuclear facilities,

AND WHEREAS they and their children now suffer or risk an array of radiation-induced injuries ranging from acute radiation syndrome to cancers, leukemias, diseases of the immune system, blood diseases, psychological disorders, reproductive impairment, and genetic diseases in current and succeeding generations,

AND WHEREAS radiation victims also suffer from an abrogation of their rights due to needless exposure, biased research, purposeful misinformation, lack of sound medical care, and denial of compensation for injuries received,

BE IT RESOLVED THAT to defend human health, to protect our genetic heritage, and to stem the erosion of citizens' rights, we adopt this **Radiation Victims' Bill of Rights:**

RADIATION VICTIMS HAVE THE RIGHT TO:

I. PREVENTION OF NEEDLESS EXPOSURE TO RADIATION

II. HONEST RESEARCH ON HEALTH EFFECTS OF RADIATION

III. FULL DISCLOSURE OF RADIATION RECORDS AND RADIATION HAZARDS

IV. COMPETENT MEDICAL CARE FOR RADIATION INJURIES

V. FINANCIAL COMPENSATION FOR RADIATION INJURIES

I. Prevention of Needless Exposure to Radiation

A. All people have the right to freedom from needless exposure in their workplaces or communities, and the right to refuse hazardous work or medical treatment.

B. People have the right to the best available means of radiation protection, including, for all radiation workers, the possession of monitoring devices that signal the presence of radioactivity as it occurs, rather than those that merely indicate afterwards that an exposure has already taken place.

C. Radiation workers have the right to the same legal and administrative protections available to other workers in hazardous industries, and those individuals who report problems have the right to safeguards for their lives and careers.

D. People have the right to independent regulation of the radiation industry.

E. Radiation victims have the right to full participation in establishing "acceptable" standards and "allowable" limits for radiation exposure.

II. Honest Research on Health Effects of Radiation

A. People have the right to have public funding for research on radiation health effects transferred from agencies with nuclear promotion mandates to agencies with public health mandates.

B. People have the right to have public funds set aside for the study of the pathways of radiation through the air, soil, water and the food chain.

D. Representatives of victims organizations have the right to serve on review committees for radiation effects research funded by the government.

E. Radiation victims have the right to a national tumor and mortality registry accessible to all upon request.

F. Radiation workers have the right to a national radiation registry.

III. Full Disclosure of Radiation Records and Radiation Hazards

A. Individuals have the right to receive comprehensive personal exposure records in clear, understandable language, or a clear statement that no such records were made or still exist for that individual.

B. Unions, victims' organizations, health agencies and other representative groups have the right to complete radiation exposure monitoring; and medical information, free of charge.

C. People have the right to accurate information and education about the physical, reproductive, and psychological effects of radiation exposure.

D. Workers have the right to be informed in advance of all radiation hazards, potential radiation hazards and hazardous materials used in the workplace.

E. People have the right to disclosure of all data regarding radiation releases of any of the nearly 500 radioactive isotopes that may be released into the workplace or the environment.

IV. Competent Medical Care for Radiation Injuries

A. All people have the right to the best available medical treatment for radiation-related diseases.

B. All radiation victims have the right to choose their health care providers or personal physicians.

C. All radiation victims, including soldiers exposed at atomic test sites, the people living near atomic test sites, nuclear facilities, or other radioactive sites, as well as the workers at those sites and facilities, have the right to appropriate screening and screening facilities in order to detect radiation-related diseases as early as possible.

D. All radiation victims have the right to representation on panels establishing or reviewing radiation screening programs.

V. Financial Compensation for Radiation Injuries

A. All radiation victims have the right to adequate compensation for physical injury, reproductive impairment and psychological distress.

B. States, counties, and localities have the right to expand compensation protections for radiation victims.

C. All individuals with documented radiation exposures or symptoms demonstrating radiation exposure have the right to legal "presumption of causation."

D. All radiation victims have the right to hold responsible individuals, corporations, and governments fully liable for negligent actions to the full extent of injuries inflicted.

Radiation Victims Roundtable
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236 Massachusetts Avenue, N.E.
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RADIATION VICTIMS BILL OF RIGHTS Sat Dec 15 1
ORGANIZATIONAL ENDORSEMENTS PAGE 1

1984 Committee
American Indian Movement
Anishinabe Akeeng
Bread & Roses Catholic Worker
Campaign Against Nuclear Power
Center for Atomic Radiation Studies, Inc
Christic Institute
Citizen Action Lasting Security (Eugene)
Citizen Soldier
Citizens Against Nuclear Power
Citizens for Safe Energy
Citizens' Energy Project
Columbia Peace Collective
Conf. Tribes of Umatilla Indians
Confederated Tribes of Grand Ronde
Critical Mass Energy Project
Dekalb Area Alliance Responsible Energy
Disarm Now Action
Downwinders
Ecology Task Force - NY Mob for Survival
Environmental Policy Institute
General Assembly to Stop the Powerline
Government Accountability Project
Grass Roots Organizing Workshop
Greenpeace U.S.A.
Hanford Education Action League
International Indian Treaty Council
Internatnl Alliance of Atomic Veterans
Iowa Socialist Party
Klein Walker Associates
Lucas Valley School of Art
Milwaukee Mobilization for Survival
Ministry of Concern for Public Health
Mobilization for Survival
N. Amer. Water Office/ Acid Rain Network
National Committee for Radiation Victims
National Lawyers Guild
New Clear Vision
NH Clamshell
NTA RVA
Nuclear Information & Resource Service
Nukewatch
NY Public Interest Research Group, Inc.
Pacific Concerns Resource Center
Pacific Peacemaker
Pacific Peacemaker Project
Palmetto Alliance
Peace House
Peace Resource Center
People's Clearinghouse

Performers for Nuclear Disarmament
Puget Sound Women's Peace Camp
Radiation Research Institute
Radiation Survivors Congress - 1984
Salitz Tribal Council (ATNWI)
Seattle Non-Violent Action Group
Seattle Nonviolent Action Group
Seattle Nonviolent Action Group
Seattle Nonviolent Action Group
Shoshone-Paiute Business Council (ATNI)
Shoshone/Paiute Tribes-Duck Valley ATNWI
Snoqualmec Tribe (ATNI)
Steilacoom Tribe (ATNI)
Student Nurses Assoc. of California
The 1984 Committee
US Nuclear Free Pacific Network
WAND - (local chapter, Otis Orchards,WA)
Wisconsin Environmental Decade
Women for Peace

RADIATION VICTIMS BILL OF RIGHTS
INTERNATIONAL ENDORSEMENTS

Australian Railway Union	Queensland
Australian Railways Union	Sydney
Campaign for the Demilitarization of the	Indian Ocean
Chamorro Grassroots Movement	Guam
CND	London
Greenpeace New Zealand	Auckland,
Hiroshima Gensuiken	Hiroshima, Jap.
Hiroshima Gensuikin	Hiroshima,
Hungrian Peace Council	Budapest
International Solidarity Conference	Gensuikin,Japan
Movement for National Independence	Athens, Greece
National Council for Peace & Solidarity	Iraq-Baghdad
Nipponzan Myokogi Buddhist Order	London, UK
Nuclear Disarmament Projects	Australia
Nuclear Disarmament Projects	Sidney,Austral.
Org. of People for Indigenous Rights	Guam
The Greens	West Germany
Women for Peace and END- FRG & Italy	Berlin

RADIATION VICTIMS BILL OF RIGHTS
INDIVIDUAL ENDORSEMENTS

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Hon. Bella S.	Abzug	
David	Albright	Federation of American Scientists
Glenn	Alcalay	US Nuclear Free Pacific Network
Maxine	Alex-Martini	Pacific Peacemaker
Robert	Alvarez	Environmental Policy Institute
Mary Sue	Amas	HEAL
Peter	Anderson	Wisconsin Environmental Decade
Albanta	Atencio	Santo Domingo Social Services (ATNI)
Tim	Baker	
Howard	Barbour	E.N.D. The Dalles
John	Bartlett	Seattle Nonviolent Action Group
Eleanor W.	Beatty	HEAL
Alan B.	Benson	Hanford Education Action League
Rosalie	Bertell Ph.D. GNSH	Ministry of Concern for Public Health
Meredith	Bliss	
Patrick F.E.	Boyle	Roman Catholic Priest
Sarah	Bransfield	
E. Cooper	Brown	National Committee for Radiation Victim
Douglas P.	Brown	Conf.Tribes of Siletz Indians (ATNI)
William H.	Burke	Conf. Tribes of Umatilla Indians
Daniel	Burnstein Esq.	Center for Atomic Radiation Studies, In
Brett	Bursey	Grass Roots Organizing Workshop
Guy D.	Burton	Citizen Action Lasting Security (Eugene
Gail	Chehak	Klamath (ATNI)
Guy	Chichester	NH Clamshell
Elizabeth	Christensen	Hanford Education Action League
Delores (Kandee)	Cleary	Seattle Non-Violent Action Group
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Julie Lynn	Couch	
Karen L.	Coulter	Columbia Peace Collective
Alta L.	Courville	Salitz Tribal Council (ATNWI)
Alvin E.	Courville	Salish Koutenai (ATNI)
George	Crocker	N. Amer. Water Office/ Acid Rain Networ
Domnich	Curley	Cda.Tribe, Cour d'Alene Tribe
Agnes	Darrah	HEAL
Elmer	Darrah	HEAL
Ruby L.	Davis	N.T.S.R.V. Assoc.
Linda	Davis Rudd	HEAL
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Cassandra	Dixon	Nukewatch
Kay	Drey	
Daniel J.	Driscoll	
Barbara	Dudley, President	National Lawyers Guild
Floating	Eaglefeather	
Leona E.	Eddy	Snoqualmec Tribe (ATNI)
Tod	Ensign	Citizen Soldier
Samuel	Epstein, M.D.,	Prev. Medicine & Community Health, U. I
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Eric	Fersht	Greenpeace U.S.A.

Mary A.	Fisher	Conf. Tribes of Siletz Indians of OR
Richard	Fleming M.D.	
Vivian K.	Ford	Seattle Nonviolent Action Group
Philip J.	Frankenfeld	U of Chicago, IL Safe Energy Alliance
Bruce K.	Gagnon	Mobilization for Survival
Sharon	Geddes	
Paul	Geiger	New Clear Vision
Joseph	Gerson	AFSC
Chellis	Glendinning	Peace & Common Security Institute
Janet	Gordon	Citizens Call
Michael	Gurian	Hanford Education Action League
Margaret	Haggin	Hanford Education Action League
John	Halsell, M.D.	HEAL
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Mike	Harrison	Hanford Education Action League
Kathryn	Harrison	Confederated Tribes of Grand Ronde
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David	Hastings	Seattle Nonviolent Action Group
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Floyd	Huen M.D.	
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Lisa M.	Hunrichs	HEAL
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John P.	Hutches	Bread & Roses Catholic Worker
Judy	Isaacs	
Cliff S.	John	Coeur d'Alene Tribe of Idaho
Dr. Carl	Johnson	
Melvin S.	Joye	Nez Pierce Tribe (ATNI)
Allan	Kanner	Law Offices of Allan Kanner
Janet S.	Karan	
Ruth	Kennedy	
Michael A.	Kennedy	Handord Education Action League
Brian	Kerkoliet	
Fran E.L.	Kosker	The 1984 Committee
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Victor L.	LaCourse	
Winona	LaDuke	International Indian Treaty Council
Susan D.	Lambert	Radiation Research Institute
Alfred	Lane III	Conf. Tribes of Siletz Indians of OR
Thomas	Leahey	Seattle CISPES
Jim	Leraher	NARS
Bennie F.	Levy	NTA RVA
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Janet	Lowenthal	Nuclear Information & Resource Service
Pamela Anne	Lowry	League of Conservation Voters
Marion	Lyon	

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INDIVIDUAL ENDORSEMENTS

Al	Mangan	
Lindsey	Manning	Shoshone/Paiute Tribes-Duck Valley ATNW
Wizard	Marks	
Sandra	Marlow	CARS/NAAV/NARS
Hilda	Mason	
Charles N.	Mason, Jr.	
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Paul	McAdams	
Anna	McAnany	Christian Against Nukes
Amy	Mickelson	HEAL
Marie	Mireau	Native American Resource Network
Melody	Moore	Citizens Against Nuclear Power
Joan	Mootry	HEAL
Al	Mootry	HEAL
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Elsie	Prater	HEAL
Merle P.	Prater	HEAL
Lanora	Queckborner	Bread & Roses Catholic Worker
Steve	Rabinowitz	Ecology Task Force - NY Mob for Surviva
Scott Lansing	Regan	
Scott	Renfro	Human Race
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Dr, Mrs Louis P	Rivei, III	
Andrew A.	Robinson	
Georgia	Rohrbaugh	
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Stephen	Schmit	
Vernon	Shake Spem	Burns Paiute Tribe (ATNI)
Joel	Shapiro	Portland Central America Solidrity Cmte
Larry	Shook	HEAL
Frank D.	Simmons	Con. Tribes of Siletz, ATNI
Craig	Simpson	War Resisters League
Donald E.	Skinner	Peace House
Normon	Solomon	People's Clearinghouse
Shelley	Soom	WAND; ESR; HEAL
Pat	Spinosa	Lucas Valley School of Art
Mr. & Mrs. J.P.	Spinosa	

Benjamin	Spock	
Lynne M.	Stembridge	WAND - (local chapter, Otis Orchards,WA)
Lynne	Stembridge	WAND; HEAL
Ernest	Sternglass	U.of Pittsburgh, Dept of Radiology
Steve	Sumerford	War Resisters League
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Mary V.	Tenorio	Pueblo of Acoma (ATNI)
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Sam	Totten	Critical Mass Energy Project
Preston Jay	Truman	Downwinders
Nancy	Uding	CISPES - Bellingham
Jasmine	Vin	Bread & Roses Catholic Worker
Bruce W.	Von Zellen	Dekalb Area Alliance Responsible Energy
Sue	Walker	W. Washington CISPES
Paul F.	Walker	Klein Walker Associates
Elli	Walters	
Kathleen	Welch	NY PIRG
Richard	Wood	Seattle Non-Violent Action Group
Pete	Wyman	HEAL

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RADIATION VICTIMS BILL OF RIGHTS
INTERNATIONAL ENDORSEMENTS BY INDIVIDUALS

Sat Dec 15
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Chose Tokyo, Japan		Korean National Peace Committee
Dr. Isam Iraq-Baghdad	Abid Ali	National Council for Peace & Solidarity
Tombopoulou Papagpos,Greece	Afrodite	Paporga Peace Committee
Hilarie Koror, Belau	Akitaya	Catholic Womens Group
Anne Budapest	Bebritz	Hungrian Peace Council
Lukas West Germany	Beckmann	The Greens
Kim Tokyo, Japan	Cavanagh	
Bjorn-Olof Vasa, Finland	Ehrnstrom	Chief Physician, Korsholm Health Center
Bernd Heidelberg, FRG	Franke	Inst. for Energy & Environmental Res.
Peter Australia	Garrett	Nuclear Disarmament Projects
Mark Montreal,Canada	Goldberg	Dept of Epidemiology & Health, McGill U
David Herts, England	Greenhalgh	
Rev. Nora London, UK	Greenway	Nipponzan Myokogi Buddhist Order
Eivind Drammen, Norway	Gronvold	Bike for Peace '85
Guido West Germany	Grunewald	DFG-VK
Koji Tokyo, Japan	Hamatani	
Jeremiah Martin Bucks, England	Hartigan	

Mikio Hodogaya-ku,	Haruna	Staff writer, Kyodo News Service
Wolfgang Waldenburg,	Hege	
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Jeffrey Francis Queensland	Jones	Australian Railway Union
Lukas Finland	Karel	World Peace Council
Dr. Thilo Heidelberg, FRG	Koch	Inst. for Energy & Environmental Res.
Dr. Rafael L. L Habana, Cuba	Lopez-Valdes	Cuban Cmte Peace & Sovereignty of People
Doreen Manachester, UK	Marchant	NFZ
Sue Vancouver	McIlroy	SNAG Vancouver (Simply No Acronym Group)
Yasuko Athens, Greece	Nakayama	Group No More Hiroshima
Sr. Helena Koror, Palau	Ngirkelan, MMB	
Keiko Hiroshima,	Ogura	Hiroshima Gensuikin
Eva Berlin	Quistorp	Women for Peace and END- FRG & Italy
Doris Sidney,Austral.	Ricono-Garrett	Nuclear Disarmament Projects
James Tokyo, Japan	Rochow	
Joan London	Ruddock	CND
Elaine Auckland,	Shaw	Greenpeace New Zealand

RADIATION VICTIMS BILL OF RIGHTS
INTERNATIONAL ENDORSEMENTS BY INDIVIDUALS

Fumiko Tokyo, Japan	Shimoda	
M.	Stombolshya	Bulgarian Peace Committee
Ven Indian Ocean	Sunnasy	Campaign for the Demilitarization of the
R. C. Sydney	Taylor	Australian Railways Union
Maria Guam	Teehan	Org. of People for Indigenous Rights
Ronald Franquez Guam	Teehan	Chamorro Grassroots Movement
Michael Athens	Tombopoulos	Greek Comm.for Internatl Detent & Peace
Susan Koror, Belau	Uass	

RECORDS SELECTED 00042

Senate Permanent Subcommittee on Investigations

EXHIBIT # 13

programs funded in whole or in part by Federal funds, and report such recommendations to the Congress within 180 days after the date of the enactment of this Act.

Investigation.
42 USC 255 note.

(d) The Secretary of Health and Human Services, acting through the Inspector General of the Department of Health and Human Services, shall undertake a thorough investigation of—

(1) the methods available to stem fraud and abuse in the provision of home health services under medicare and medicaid; and

(2) the extent to which such methods are applied in stemming such fraud and abuse.

Report to Congress.

The Secretary shall report the results of the investigation to the Congress within 18 months after the date of the enactment of this Act.

42 USC 255 note.

(e)(1) The Secretary of Health and Human Services shall develop and carry out demonstration projects commencing no later than January 1, 1984, to test—

(A) methods for identifying patients at risk of institutionalization who could be treated more cost-effectively with home health services and other non-institutional health services; and

(B) alternative reimbursement methodologies for home health agencies in order to determine the most cost-effective and efficient way of providing home health services.

(2) Methods for identifying patients at risk of institutionalization to be tested by the Secretary under paragraph (1)(A) may include, but not be limited to, the identification of hospitalized medicare patients who are candidates for early discharge due to availability of home health services and individuals in the community who could avoid institutionalization with the availability of home health services.

(3) Reimbursement methodologies to be tested by the Secretary under paragraph (1)(B) may include but not be limited to fee schedules, prospective reimbursement, and capitation payments.

Report to Congress.

(4) The Secretary shall report to Congress his findings with regard to the demonstrations carried out under paragraph (1) no later than January 1, 1985.

"Home health services."
42 USC 255 note.
42 USC 1395x.

(f) For purposes of this section, the term "home health services" has the meaning prescribed for the term by section 1861(m) of the Social Security Act.

ANALYSIS OF THYROID CANCER; ACTIONS BY SECRETARY

42 USC 241 note.
42 USC 241.

SEC. 7. (a) In carrying out section 301 of the Public Health Service Act, the Secretary of Health and Human Services shall—

(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

Report to Congress.

(4) prepare and transmit to the Congress within one year after the date of enactment of this Act a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

Radioepidemiological tables, publication.

(b)(1) Within one year after the date of enactment of this Act, the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish—

(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

Update of tables.

(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise. The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise.

TECHNICAL AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

SEC. 8. (a) Section 207(a)(1) of such Act (42 U.S.C. 209(a)(1)) is amended by inserting "psychology," after "pharmacy,".

(b) Section 306(1)(2) of such Act (42 U.S.C. 242k(1)(2)) is amended by striking out subparagraph (D) and redesignating subparagraphs (E), (F), and (G) as subparagraphs (D), (E), and (F), respectively.

(c) Section 308(d) of such Act (42 U.S.C. 242m(d)) is amended (1) by inserting ", if an establishment or person supplying the information or described in it is identifiable," after "No information", and (2) by striking out "authorized by guidelines in effect under section 306(1)(2) or under regulations of the Secretary" and inserting in lieu thereof "such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose".

(d) The first sentence of section 311(c)(2) of such Act (42 U.S.C. 243(c)(2)) is amended by striking out "forty-five days" and inserting instead "six months".

(e) Section 330(d)(2) of such Act (42 U.S.C. 254c(d)(2)) is amended by inserting before "and the costs" the following: ", the costs of repay-

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